

## **MASTER'S FINAL PROJECT**

Track: In Company Project

Track Coordinator: Ignasi Algueró

**Title: The Potential Impact of Health IT Companies  
on Healthcare Industry - Based on Mint Labs Inc.**

Organization: Mint Labs Inc.

Programme: MSc in International Management

Course 2015-2016

Student: Alara Alkin

Tutor: Mario Schafer

**CONFIDENTIAL**

## TABLE OF CONTENTS

I.	INTRODUCTION	3
II.	EXECUTIVE SUMMARY	4
III.	THE INDUSTRY	13
IV.	MINT LABS	
	a. History	21
	b. Activities	23
	c. Competitors	26
	d. Competitive Advantage	34
	e. Barriers of Entry to Market	36
	f. Business Model	37
V.	HYPOTHESIS	52
VI.	VALIDATION	53
VII.	RECOMMENDATION	64
VIII.	REFERENCES	68

## I. INTRODUCTION

The aim of this in company project is to understand the healthcare industry and to figure out if advanced software companies such as Mint Labs can have lasting and disruptive effects on aspects of the value chain of the industry with their technologies.

The focus will be on Mint Labs who provides a cloud-based platform with advanced data management, data analytics, and 3D visualization on neuro images sourced from different machines and systems.

The value chain of the pharmaceutical companies will be scrutinized to analyze the industry with an emphasis on the clinical trial process as Mint Labs' platform can create value for the clinical trial stakeholders within the industry with its features.

The founders of Mint Labs believe that the platform's numerous tools and offerings would ease all the data processes and patient selection currently still done manually and/or with observation by transforming them into automated processes, thus, substantially decrease time, money, and effort spent on data management and analysis. They foresee that this will accelerate the drug discovery and development processes to a large extent. The potential impact or disruption of the Mint Labs' platform stems from this claim. According to Clayton M. Christensen of Harvard Business School, a disruptive innovation can be defined as a product or service that starts slow and tirelessly moves up in the market to finally displace established competitors. (Winter, 2016) Thus, Mint Labs' potential impact can also be referred to as a disruptive innovation as it started slow, is moving up in the market to reach the clinical trial stakeholders to change how they do things and replace all that with one platform.

The in company project will thus, first, analyze the healthcare industry and the clinical trial process. Then, Mint Labs will be examined from various aspects which can be listed as: the history, the activities, the competitors, the competitive advantage, the barriers of entry to the market, and the business model, which is the most crucial part. According to

the information gathered from diversified sources, a hypothesis will be stated. This hypothesis will be validated with interviews conducted with a number of experts with different backgrounds and positions in the healthcare industry representing different stakeholders. Lastly, recommendations will be delivered for the company to bolster its chances of achieving its goal and impact with respect to the research done on the industry, the experts' opinions, and observations.

## **II. EXECUTIVE SUMMARY**

The goal of the in company project is to determine if the company analyzed, Mint Labs, will be able to exquisitely follow its roadmap to fully realize its business plan and accomplish all of its objectives. The two primary future aims of the company is to become a gold standard in clinical trial processes by accelerating the discovery and development of new treatments and to build the biggest brain database in the world. It can be claimed that the company's platform will be a disruptive innovation following HBS professor Clayton M. Christensen's definition of a product that moves up in the market to finally replace the status-quo. (Winter, 2016)

To fully understand how Mint Labs can create value with its platform and what are the unmet needs in the industry, a comprehensive industry analysis was performed. The pharmaceutical companies used to be in full control of the value chain starting from the R&D till the sales of the products. (Jac, 2013) With the trends of increasing costs, higher financial burden on patients, and growing needs in emerging countries, the industry entered the path of following new business models as the already long and expensive process clinical trials have elongated with most drugs failing at various stages of the trial. (PwC, 2009; James, 2010) Thus, most of the pharma companies now outsource part of or all of their operations in order to minimize cost and share risks. (PwC, 2009)

The reasoning behind this trend stems from the clinical trial processes where phase 0 takes 3 to 6 years, phase I 1 to 2 years, phase II up to 2 years, phase III up to 4 years

because the number of patients involved and the level of examination rises with each phase. (NIH, 2016) Less and less candidate molecules of drugs move onto the next phase as the process goes on with only 25 to 30 % of drugs passing to the last phase to apply to be approved by the FDA. (FDA, 2016) As can be expected, the cost of each phase also increases with the number of patients, thus, number of tests, images, investigators, etc rising. (ASPE, 2014) This results in a final total cost varying from \$161 million to \$2 billion per drug where the average comes to \$1.3 to 1.7 billion and the range is explained by the inherent differences between diseases under trial. (ASPE, 2014) On top of that, the costs are growing at a rate of 7.4% every year because of bigger patient pools to identify differences between new and old drugs and because of the focus on chronic and degenerative diseases, which makes trials last longer. (ASPE, 2014) Additionally, there are various barriers to successfully completing trials such as high costs, difficulties in patient recruitment and retention, and regulatory burden. (ASPE, 2014) However, these barriers can at least be lowered by incorporating new technologies, software, and tests into the process, such as Mint Labs' platform, which can lower costs and timespan of trials. (ASPE, 2014)

These are still tens of millions of people suffer for brain diseases; 46.8 million from Alzheimer's Disease and 50 million from epilepsy to name only a few. (AZ, 2016; WHO, 2016) Moreover, we know neither the causes nor mechanisms of most of the brain diseases, thus, most of these diseases are still incurable. The issues with clinical trials makes it very difficult to conduct new trials for these currently impossible to cure diseases, however, this is paramount for the future as the prevalence of these diseases will continue to increase. With CNS diseases such as Alzheimer's, Parkinson's, and MS, the only non-invasive way to examine the brain is neuroimaging, thus, neuro images are becoming vital tools for early diagnosis and monitoring of clinical trials and treatments. (Jnguyen, 2012)

Additionally, the burden of the neurodegenerative diseases has already come up to €800 Billion in Europe and more than \$1.5 Trillion in the US (Diluca, 2014; Greene, 2016), and, on top of that, the failure rates of the clinical trials performed for central nervous system diseases is more than 85% where one of the major causes of this failure is insufficient understanding of mechanisms underlying brain diseases. (Skripka-Serry, 2013)

Furthermore, the company believes that the patient selection process of clinical trials require much more efficiency and the tools of Mint Labs can match patients with trials, thus, effective drugs can be put on the market faster. Currently, a combination of medical images (qualitatively inspected), motor function tests, EDIS scores, and subjective questionnaires are used to select patients for clinical trials. However, as mentioned before, as most of the mechanisms of the brain are unknown, this inefficient patient selection results in elongation of the trial as it is very difficult to measure the impacts of very specified drugs on patients who are not directly suited for the drugs.

Thus, all the burdens of the clinical trial stakeholders can be diminished with support from software and technologies developed by experts and scientists, such as the solution of Mint Labs, as, if clinical trials were performed in a more efficient manner, years can be deducted from their timespan and the percentage of drugs that pass the end phases of clinical trials can be significantly improved. This will bolster the efforts in early diagnosis and treatment with more clinical trials conducted and more molecules discovered.

Moving onto Mint Labs, the company was co-founded by Paulo Rodrigues and Vesna Prchkovska, who met during their PhD studies at Eindhoven University of Technology, where they grasped that Magnetic Resonance Imaging is a very powerful tool to look inside the brain in a non-invasive way. MRIs offer in-vivo view of the human brain, thus they can be used to develop neuroimaging tools that help understand better the brain and the evolution of diseases in a non-invasive way; they provide objective and

quantitative measurements of the tissue properties inside the brain to evaluate the efficacy of drugs and provide better patient characterization by dividing the patients into sub-categories depending on where and how advanced their brain damage is. (Shiel, 2016) This is crucial regarding the problems in patient selection. MRIs have a lot of valuable information imbedded that cannot be all accessed through qualitative observations. Dr. Prchkovska and Dr. Rodrigues believed that computational tools were necessary to make sense of this large amount of data at once, as current tools cannot handle complex data or integrate data from different machines/systems; thus, they created the Mint Labs platform.

The platform is a cloud-based software that comprises various tools for the collection, management, analysis, storage, visualization, and sharing of imaging data. Now, focusing on brain MRIs, the platform will be able to accommodate PET and CT data in the near future. The platform works in this way: researchers or doctors upload their multimodal imaging data to the platform; the data is automatically de-identified and standardized; the data is then put into storage; the tools on the platform processes the data and runs analyses; the users can visualize the results of analyses in 3D and touchless; lastly, they can share the results with their colleagues and collaborators. Imaging biomarkers are utilized for advanced detection. The pipelines of the platform allow the standardization of data and advanced processing where patterns in the data can be discovered much more quickly and effectively, which can result in a decrease in time span for early disease detection. 3D visualization is crucial for the researchers and doctors to explore the brain on a whole new level as it provides full insight. These features all make the platform the perfect tool to support the research of the neurologists and other clinical players who have vast amounts of data but do not have the sophisticated tools to analyze them and rely on qualitative observations and manual systems. The end goal of Mint Labs is to become “the milieu” for all imaging data and other supporting data to have the biggest brain database in the world to develop the most

advanced machine learning algorithms, and thus become a gold standard for clinical trials. The company foresees that this will accelerate the discovery and development of new treatments for central nervous system diseases.

One of the possible barriers to achieving this goal are the company's competitors that span across the industry as the platform offers various solutions in one. These competitors can be listed as imaging informatics platforms that provide open-sourced solutions for analysis of images, advanced neuroimaging providers that offer tools developed by imaging experts for imaging experts, cloud storage providers who have standard storage offerings, Vendor Neutral Archives (VNAs) which are local storage systems for medical images, and, lastly, imaging biomarker providers who offer biomarkers for precise detection of diseases in medical images. Luckily for Mint Labs, none of the competitors offer as many features as Mint Labs does and most of them do not have an emphasis on brain with algorithms specifically created for these purposes. Imaging Informatics platforms such as XNAT offer open-sourced solutions and are intended only for expert researchers. Cloud storage providers such as CareStream and GE Health Cloud do not have a specific focus on imaging or brain but provide storage for all medical imaging and other data, but only offer cloud services. Advanced neuroimaging providers such as Olea and BrainInnovation, in contrast to imaging informatics platforms, have advanced proprietary tools developed by imaging experts for imaging experts, but require high scientific and technological know-how to be handled properly. VNA systems such as Acuo and Siemens, similar to cloud providers, provide only a storage solution that is not intuitive. Imaging biomarker providers such as Quantib and NeuroQuant do offer access to advanced algorithms to carry out analysis using the imaging biomarkers, which is vital for the advancement of medical research, especially for diagnostic and monitoring purposes of CNS diseases. However, the handling of these biomarkers also require expert know-how if not provided on easy-to-use way such as on Mint Labs' platform. The competitors that are FDA compliant or CE marked have an



advantage over Mint Labs as Mint Labs will be FDA compliant and CE marked by the end of 2017, which provides them a time-frame to grow with less competition. Nevertheless, what Mint Labs offers is all of these critically important solutions on the same platform, in the most simplified and easy-to-use way; it is not only intended for experts with coding know-how. On top of that, with Mint Labs, the researchers have access to both open-sourced imaging informatics and proprietary advanced imaging tools through a cloud-based platform. The company also supplies biomarkers for CNS diseases such as MS and AD and the number of tools and biomarkers the platform offers will increase over time as with collaborations and partnerships.

Furthermore, there are various barriers of entry to the market which is advantageous for Mint Labs. First, Mint Labs has unique and proprietary data analytics tools that were developed over the years and advanced even further by the experts, thus development of these tools or similar ones from scratch would take years of hard work. Second, if everything continues on the current course, Mint Labs' customer base will exponentially grow with clients from all over the world adapting to the platform and with the early adoption of the platform, it would be highly challenging for a new company to come in and convince all the synced users to change to using their system. Lastly, the high financial requirements of the research and development of such advanced platforms makes it very difficult to start new companies.

The business model of Mint Labs should be examined next to assess its objectives to figure out if the company's platform will create an impact as in the case of a disruptive innovation. Business model canvas method will be utilized as it provides a structured way to dissect the components of the business model with emphasis on the strategic implications of each aspect. (Osterwalder, 2013) The value propositions of the company can be listed as: its all-in-one platform, cloud-based access, automatic data de-identification & standardization, HIPAA compliance for privacy of data, analysis with proprietary & open-sourced tools, reproducible results, 3D and touchless visualization,

and easy sharing. Its customers are individual researchers or teams of researchers, large and top-notch research organizations & hospitals, and CROs & pharmaceutical companies. The main channels to reach these customers are face-to-face at international medical conferences and symposiums, and online through LinkedIn, Twitter, Facebook, Research gate, Academia, and Newsletters. The relationship with these customers becomes more personalized and more attentive from individuals moving up to big clients such as major hospitals and CROs. The key partners of the company are Google and Amazon Web Services as the cloud providers and hospitals or research organizations who provide data and possibly analytics. Possible partnerships can be built with hardware or VNA vendors, biotech companies or CROs, and Electronic medical/health record providers. Key resources of the company are cloud infrastructure, public and private patient data (medical images), algorithms and tools, and people (employees). The key activities of the platform can be listed as integrative data collection, advanced data management, state-of-the-art analysis, 3D and touchless visualization and easy sharing by admin/owner defined access settings. The main revenue streams of the company are pay-as-you-go & subscribed clients as part of the Software as a Service (SaaS) revenue model from hospitals, research organizations, and CROs in near future, special projects with top-notch institutions and grants. The costs primarily stem from personnel's salaries, in addition to that, the cloud storage & processing and marketing & sales activities.

Regarding the information above accumulated from research on industry, the examination of Mint Labs and the company's business model, the hypothesis is that Mint Labs' business model is valid and the company will reach the clinical trial stakeholders who would benefit from the company's product, thus, the company will become a gold standard, change how the data is managed, analyzed, visualized, and shared, and how patients are selected to clinical trials. Mint Labs' platform would have a great impact on

the healthcare industry, thus, its effect can also be referred to as a disruption for the clinical trial processes.

This hypothesis was validated by conducting interviews with experts in the industry: CEO of Cyntegrity, Dr. Artem Andrianov; Trifermed CBDO's Vice President of Business Development Dr. Clara Nascimento; Dr. Harald Jainta, Head of Business Development at Desitin Arzneimittel GmbH; Dr. Enric Gibert, CEO of Pharmacelera; Johnson & Johnson Turkey's CEO Ozgur Tomruk; Deniz Akdemir from IMS Health Turkey's commercial and market strategies department; and lastly, Mint Labs' CEO Dr. Paulo Rodrigues. The experts were asked whether they thought Software as a Service revenue model was right for Mint Labs, whether the company would be able to reach the clinical trial stakeholders with the current status quo of relying on word-of-mouth, if not, what changes were needed to reach them, which companies would be interested in partnering with Mint Labs, and whether the platform would be able to disrupt the pharmaceutical value chain.

The answers were mostly similar and complementary, however, some very interesting points were addressed by different experts according to their experiences. Firstly, the Software as a Service model was found suitable with its free trial and pay-as-you-go components being advantageous for researchers with limited funds and subscriptions being fair for big teams in large hospitals, research centers, and CROs. However, it was recommended that a bigger variety in pricing should be available for different segments with varying needs to be more fair and that more free services should be available for researchers. These free services should be in exchange of PR activities and referencing. Secondly, a number of recommendations were provided to reach the clinical trial stakeholders such as implementing all changes related to compliance necessary to pass an audit by a pharmaceutical company. Moreover, more marketing & sales activities with solid positioning should be carried out and more white papers and publications proving the benefits of the platform and presenting how neuroimaging can make a difference

should be published. On top of that, the experts supported the idea of participating to international medical symposiums and conferences to meet the important stakeholders and recommended more exhibiting activities to be performed. Another critical point was to involve key opinion leaders of the industry to gain more recognition. Most of the experts proposed a focus on Contract Research Organizations among the clinical trial stakeholders. This idea was backed up by the CEO however, he pointed out the compliance requirements to work the CROs that the company currently lacks, thus, this can be carried out in the near future.

Third, most experts believed that a number of companies who are similar to Mint Labs in growth stage, and research organizations or hospitals with substantial amount of data would be good candidates to partner up with. An expert warned to not lose the focus on investors and relationship building with them to make sure the company has enough funds; he also suggested the company to apply to more grants. Another expert proposed hiring experienced employees for marketing & sales activities in addition to partnering with hardware vendors.

The experts all believed that Mint Labs' technology will result in change on some level on how research and trials are conducted for CNS diseases, as was pointed out by the company's CEO. Some of the experts, lastly, suggested an advancement of the platform to contain more body parts as an opportunity to grow or partnerships with high tech giants such as Apple as possible activities in the future. The possibility of incorporating new body parts is still on the roadmap according to Dr. Rodrigues, CEO of Mint Labs, although it is risky for now, it would be a straightforward development if desired.

To conclude, recommendations were presented for the advancement of the business model and for the roadmap of the company based on the recommendations of the experts, the literature review on the industry and similar companies, and observations. The close relationships with researchers should be continued and advanced to a new level with PR activities. More collaborations and partnerships should be carried out with

other companies, hospitals and research centers. The company should implement the necessary additions on the platform and become FDA compliant and ISO certified as soon as possible. Marketing & sales experts should be hired to reach the targeted niche segments in the best way with solid positioning both online and offline using social media, newsletters, and exhibitions in conferences. Relationships with all customers and investors should be efficiently and closely managed. The company should apply to more grants and make deals with more investors to not experience liquidity problems while growing. The company should look for opportunities to partner with hardware or VNA vendors and high-tech companies. Lastly, the company should consider adding analytics on other parts of the body to grow in new areas. Consequently, the objectives of Mint Labs are realizable if the company follows the recommendations.

### **III. THE INDUSTRY**

The pharmaceutical industry has always been following a business model that is referred to as Fully Integrated Pharmaceutical Company (also FIPCO). The reasoning behind this was that the focus of the companies was on the development of the pharmaceutical products. (Phillips, 2016) The companies were in full control of the value chain starting from the R&D till the sales of the products, some of the big pharma still are. (Jac, 2013) With the trends of increasing costs, higher financial burden on patients, growing needs in emerging countries the industry entered the path of following new business models. (PwC, 2009) This progress stems from the requirements of the clinical trials that is behind every drug. Unfortunately, with the increasing complexity of diseases such as cancer, CNSs, or infections from viruses, the already long and expensive process clinical trials have elongated as most drugs fail at various stages of the trial. (James, 2010) The reasoning behind this is the peaked failure rates, higher than 75%, as drugs go through challenging phases to be approved. (Grainger, 2015) Only 20 drugs are approved per year. (James, 2010)

A number of companies went onto federated models or fully diversified models; the newly entering companies and/or those with the highest entrepreneurial spirit adopted the virtual variant of the federated model, which can be also referred to as Virtually Integrated Pharmaceutical Company (VIPCO). In this case, one of the main goals is to minimize the cost by outsourcing all the operations of the company to those that can accomplish the tasks at the minimal cost while attaining a competitive advantage. (PwC, 2009) The other significant aim is to minimize the risk that comes with big investments. By sharing the risk with other a third party, while holding the intellectual rights intact of course, pharmaceutical companies minimize their risk while possibly maximizing their return on investment. (PwC, 2007) All of the activities are controlled by the center, just acting as a management. (PwC, 2009) This allows the companies to focus on what they do best, focus on innovation and growth, and efficiently use their capital. (PwC, 2009) Furthermore, to grasp the reasoning behind this movement, the clinical trial process of pharmaceutical companies, where the efficacy and safety of new treatments are measured, should be examined. (NIH, 2016) Clinical trials are constructed by a group of clinical researchers led by a principal investigator (PI) who is generally a doctor. (NIH, 2016)

The types of clinical trials can be listed as: natural history studies where to explore the progression of the disease and health; prevention trials to find better ways to prevent diseases from occurring or reoccurring; screening trials to determine the best way to detect conditions; diagnostic trials to come up with better tests or procedures for diagnosis; treatment trials to experiment on new treatments/therapies or combinations of drugs or new surgical processes; and quality of life trials to discover treatments to improve the quality of life for people suffering from chronic diseases. (NIH, 2016)

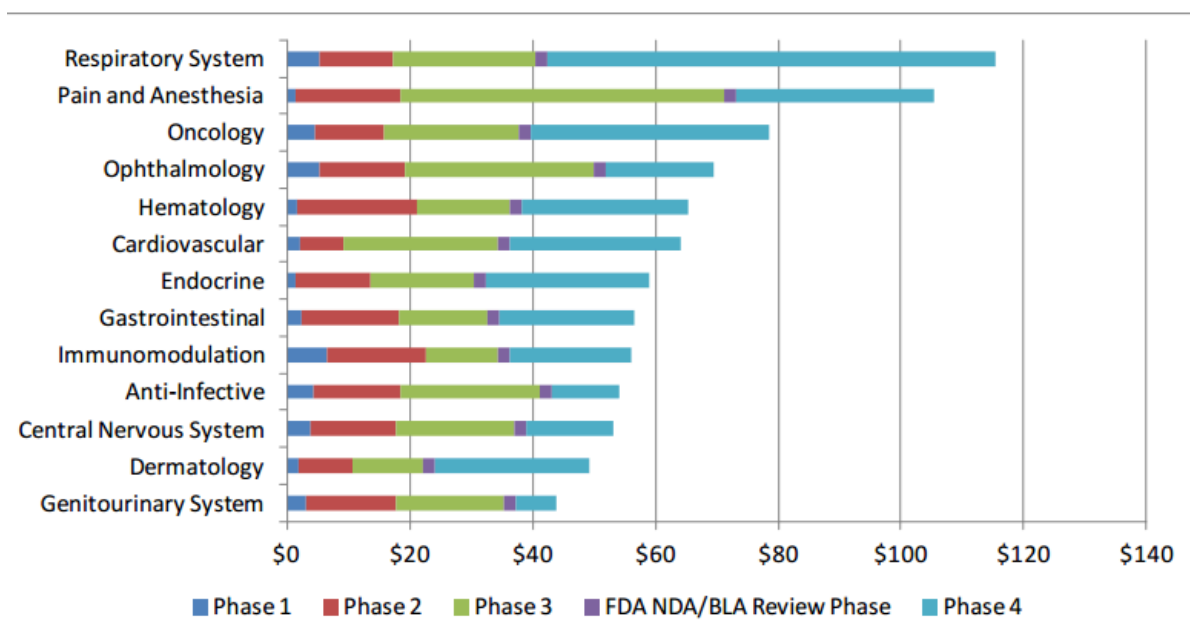
For all the types of the clinical trial process, tens of thousands of molecules are screened in laboratories and in vivo (on animals) before being selected (approximately only 5) to

be experimented in clinical trials. (NIH, 2016) This process, phase 0, takes 3 to 6 years. (NIH, 2016)

In phase I, the drug or treatment is experimented on a small group of people of 20 to 100 to assess its safety and determine its adverse effects by administering the drug at different dosages. (NIH, 2016) The flow of the drug in human body, its absorption, metabolization and excretion is identified. (CenterWatch, 2016) 70% of experimented molecules pass this phase. (FDA, 2016) In phase II, a larger group of people of 100 to 300 participates to figure out the effectiveness of the drug and further examine its safety. (CenterWatch, 2016) This phase takes up a much longer time (up to 2 years) where one group of patients receive the drug and the other - “control” - group receives a placebo and neither patients nor doctors know who is taking which one. (CenterWatch, 2016) Only 33% of the drugs pass this phase. (CenterWatch, 2016) Moving onto phase III, with a very large group of 300 to 3000 people, a very detailed examination process is carried to fully understand the effectiveness of the drug in addition to the benefits and side effects. This lengthy process may take up to 4 years and only 25 to 30 % of drugs pass this phase to apply to be approved by the FDA. (FDA, 2016) Only 80% of those get the final approval to be marketed. (Berkrot, 2011) Then comes phase IV where the examination is done on a drug that is already in the market to compare it to competitor’s drugs, to test the effectiveness of the drug in the long run, thus its impact on the patient’s quality of life, and, finally, to check the cost-effectiveness of the treatment. (CenterWatch, 2016) Depending on the results of this phase, the drug’s manufacturing can be restricted or stopped. (CenterWatch, 2016)

Unfortunately, only one in ten drugs eventually reach the market but the sponsors of clinical trials (physicians, foundations, medical institutions, voluntary groups, pharmaceutical companies, or federal government agencies such as National Institute of Health in US) would have spent millions on the various phases of the trial even if everything goes to waste. (Bio, 2014; NIH, 2016)

According to the US Department of Health & Human Services' Office of the Assistant Secretary for Planning and Evaluation (ASPE), as can be guessed from the increasing number of patients involved, the average costs of phase III and IV are \$20 million whereas the cost is \$13.3 million for phase II and \$3.8 million for phase I; regarding Table 2. (ASPE, 2014). This results in a final total cost varying from \$161 million to \$2 billion per drug where the average comes to \$1.3 to 1.7 billion; the range is this wide because of the differences in the medical areas (stemming from the natural characteristics of diseases), number of patients, etc. (ASPE, 2014) The significance of the differences can be seen from the graph below:



Graph 1: Differences in Spending According to Diseases and Phases of Clinical Trials (ASPE, 2014)

Another finding of the study was that the costs were rising 7.4% every year. (ASPE, 2014) There are two other major factors influencing these high costs. Firstly, most new drugs are variations of older drugs, thus, to identify the “significance” of the changes a larger pool of patients is necessary, which results in more expenditure on all the phases and components of the cost. (ASPE, 2014) The second factor is actually due to the aging population trend in the world which resulted in a higher number of clinical trials conducted



for chronic and degenerative diseases that require much more expensive testing for diagnosis and monitoring, more years, and of course, more patients. (ASPE, 2014)

Additionally, there are various barriers to successfully completing the trials. The most obvious ones are of course the high costs, as mentioned earlier, and the long years, 10 to 15 on average, it takes from the molecule discovery to market the drugs. (ASPE, 2014)

The patient recruitment process is also challenging because there are either a high number of patients but a number of companies carry out trials on the same subject or there is only a small group of patients who are willing to participate to trials. (ASPE, 2014)

This is partly because of the stereotypic beliefs on the clinical trials that cause fear and partly because of the highly selective enrollment process. (ASPE, 2014) On top of that,

as the trial processes are long or the drugs may create side effects or other problems, patients may drop out, which might terminate the study. (ASPE, 2014) Because of

various factors mentioned above, pharmaceutical companies outsource the clinical trial process to only a small number of clinical research organizations (CROs) that are trusted strategic partners. Healthcare experts also state that there is a shortage in researchers,

statisticians, and clinical investigators in the US, however this is not valid for EU. (ASPE, 2014) Probably the biggest hassle stems from the tough regulatory requirements of

agencies such as FDA as even though they aim at protecting the participants of the clinical trials and the sake of the society, they have turned into a barrier because of the

endless paperwork, legal issues, processing times, and the repetitive applications for different countries. (ASPE, 2014)

The experts came up with the following to lessen the burden of the clinical trial process: using electronic health records, having less enrollment restrictions, simplifying protocols,

decreasing source data verification, increasing usage of mobile technologies, adapting to testing at home, moving to lower-cost facilities, and, of course, revising the efficiency

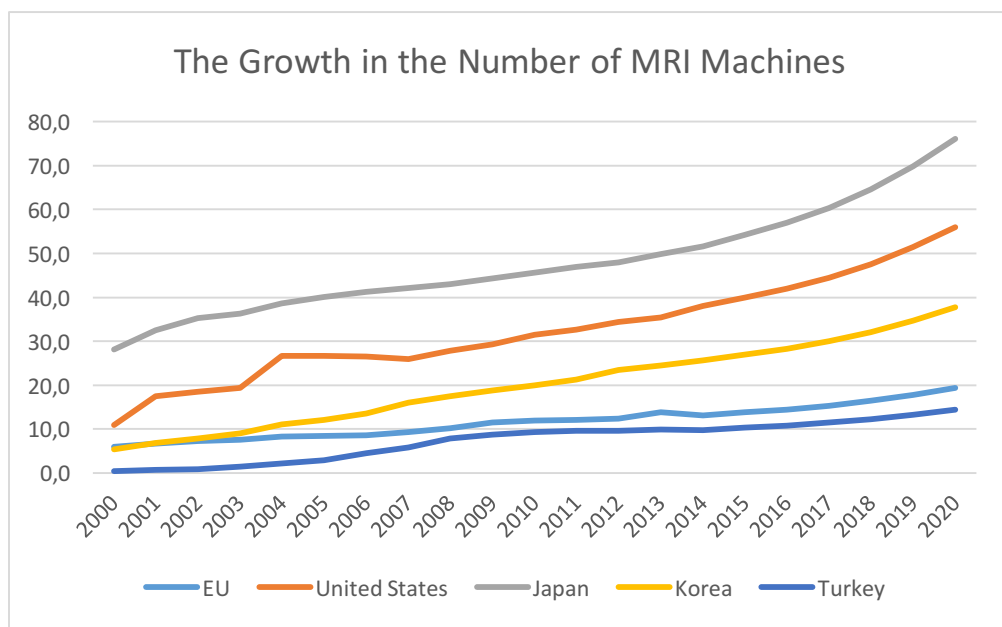
of the FDA's reviewing process. (ASPE, 2014)

Getting into detail to show the effect of the improvements mentioned above, regarding what Mint Labs offers, the impact of using electronic health records and mobile technologies can be examined. First, incorporating electronic health record usage into the clinical trial process would save time and cost while making sure that the doctors have recruited the most appropriate patients as the researchers or doctors will have access to the full medical history of the patients that would like to participate. (ASPE, 2014) According to a study by Deloitte, the attrition rate of patients selected by examining EHR is 50% lower than that of regular selection, which would affect the cost of patient recruitment. (ASPE, 2014) Additionally, utilizing EHR has decreased costs for all the phases of the trials in all areas of medicine, the reduction ranging from 3% to 9%, which comes to \$0.4 million to \$ 4.7 million. (ASPE, 2014) Second, benefitting from mobile technologies throughout the various phases of the clinical trial will support both the patient selection and the monitoring processes for the clinical trials. (ASPE, 2014) This will result in a decrease in costs ranging from 3% to 14% per phase, which comes to \$0.5 million to \$ 6.7 million. (ASPE, 2014)

Thus, if such changes are realized, the time span of clinical trials, thus the cost of the trials will decline. (ASPE, 2014) This will, in turn, boost the development of new treatments as the burden of sponsoring trials will decrease which means a higher number of clinical trials may be supported with the same budget. This will benefit both the pharmaceutical companies and the society as they will be able to put more drugs on the market in less time and patients will have more options and / or better options to choose from.

Unfortunately, despite all the ceaseless developments in technology, science, and medicine, still, tens of millions of people suffer for brain diseases; 46.8 million from Alzheimer's Disease, 10 million people from Parkinson's Disease, 2.5 million people from Multiple Sclerosis, and 50 million from epilepsy to name only a few. (AZ, 2016; PDF, 2016; Pietrangelo, 2015; WHO, 2016)

As brain is still mostly a black box, we do not know the causes or mechanisms of most of the brain diseases, thus, most of these diseases are still incurable. This creates an enormous need for ways to examine the brain. One of these ways, the only non-invasive one, is neuroimaging. (Jnguyen, 2012) Neuroimaging can be defined as producing images of the brain without incision or direct contact to show the structure and functionality of the brain. (Jnguyen, 2012) Neuroimaging is rapidly growing and utilized for this exact reason. The graph below drawn from OECD data shows the increasing importance of MRI.



Graph 2: The Growth in Number of MRI Machines (OECD, 2015)

With the rise in diseases by both external factors and aging populations, the significance of non-invasive methods such as MRI will continue to grow, as seen above.

Currently, most of the fatal neurological diseases are diagnosed too late. In the case of Parkinson's Disease, for instance, diagnosis is only possible in the presence of motor markers such as tremor, rigidity, slowness and, unfortunately, after that point, slowing the disease is nearly impossible as severe brain damage has already occurred. (PDF, 2016) A similar case is valid for Alzheimer's Disease as the disease has common

symptoms with other neurological diseases such as depression, dementia, thus it is very problematic to diagnose Alzheimer's. (Alz, 2016) Hence, early diagnosis for diseases such as Parkinson's or Alzheimer's or other grave neurological diseases is crucial for recovery.

In addition to this, it is necessary to state the burden of such diseases on health care system and pharmaceutical companies to grasp the severity of the problem and to show how a solution such as that of Mint Labs can change the industry. To begin with Europe, the yearly cost of brain diseases on the public health expenditure comes up to €800 Billion. (Diluca, 2014) With the aging population in Europe, this is expected to increase. Similarly, in US, the annual cost of mental and neurological disorders and diseases is more than \$1.5 Trillion, or 8.8% of Gross Domestic Product (GDP). (Greene, 2016) On the other hand, the cost of drug development for Central Nervous System (CNS) Disorders come to \$80 Billion a year for pharmaceutical companies and, on top of that, more than 85% of the drugs under development fail miserably. (Skripka-Serry, 2013) This results in less pharmaceutical companies investing in research and development of CNS related drugs. Since 2011, GlaxoSmithKline, AstraZeneca, and Novartis have closed down and Pfizer, Sanofi, and Merck have downsized their CNS drug development departments. (Skripka-Serry, 2013) The major causes behind the failures in R&D of CNS drugs are stricter FDA regulations for CNS diseases, insufficient understanding of mechanisms underlying brain diseases, the challenges in running clinical trials, especially the placebo effect.

As stated earlier in detail, the clinical trial process is very burdensome. There is not much that can be done on the strict FDA regulations that have to be abided to, however, there is a lot that can still be achieved for understanding better the brain and the mechanisms of diseases. In addition to this, the whole process of clinical trials can also be supported in numerous ways, starting from better patient recruitment to better disease diagnosis and monitoring methods as, the currently utilized tests and questionnaires result in

subjective and years-long diagnostics, by when the diseases are in late stages. (EMEA, 2008)

All these can be and should be supported by software and technologies developed by experts and scientists, such as the solution of Mint Labs, to improve the clinical trial processes. This is vital for the wellbeing of the industry and to help the growing number of people suffering from CNS diseases. If clinical trials were performed in a more efficient manner with better patient selection and with the support of objective diagnosis and assessment criteria, years can be deducted from how long it takes to complete a clinical trial and the percentage of drugs that pass the end phases of clinical trials can be significantly improved. The visualization and quantification of the trials' results are necessary to prove the effectiveness of drugs.

#### **IV. MINT LABS**

##### **a. History**

Mint Labs' co-founders met during their PhD studies at Eindhoven University of Technology. Paulo Rodrigues focused on developing novel tools for the virtual dissection of the brain's white matter structures whereas Vesna Prchkovska concentrated on the processing and visualization of high angular resolution diffusion imaging (HARDI) data. During their studies, they realized that Magnetic Resonance Imaging is a very powerful tool to look inside the brain in a non-invasive way but it is either underused or the imaging data is not efficiently interpreted.

The MRI scanner's magnet creates a powerful magnetic field that causes the protons of the hydrogen atoms first to line up and then to spin due to the radio waves throughout our body. (Shiel, 2016) When they return to their original unexcited position, this creates a signal that is received by the scanner and processed to create an image. (Shiel, 2016) This very detailed image shows even the smallest changes, disruptions, or anomalies to the organ or tissue that would have been missed otherwise, sometimes with the help of

contrast agents. (Shiel, 2016) The images are used by doctors and researchers to diagnose patients and/or to monitor them during treatment or clinical trials. (Shiel, 2016) MRIs offer in-vivo view of the human body, thus they can be used to develop neuroimaging tools that help understand better the brain and the evolution of diseases in a non-invasive way; they provide objective and quantitative measurements of the tissue properties inside the brain to evaluate the efficacy of drugs and provide better patient characterization by dividing the patients into sub-categories depending on where and how advanced their brain damage is. (Shiel, 2016)

As mentioned before, tens of millions of people suffer from brain diseases, most of which are incurable. With better and easier diagnosis and monitoring, they believe that researchers and doctors can save valuable time and expenses to focus on their research and patients. MRIs have a lot of valuable information imbedded that cannot be all accessed through subjective observations. Computational tools are necessary to make sense of this large amount of data at once as current tools cannot handle complex data or integrate data from different machines/systems, thus they are not intuitive for specialists or doctors and cause inefficiencies. After grasping how crucial MRIs are and can be regarding the factors mentioned above, Vesna and Paulo realized that the MRI scans can be used to support the development of new treatments for brain diseases.

To delve into their experiences, Paulo Rodrigues is a Portuguese who studied computer science and systems engineering at University of Minho in Braha, Portugal and worked for an innovative IT company in Portugal before starting his PhD studies at Eindhoven University of Technology's Department of Biomedical Engineering's Biomedical Image Analysis group. After finishing his PhD, he worked for a successful Dutch IT company as a software engineer. Then he came to University of Barcelona as a research associate for the Faculty of Psychology's Department of Personality where he explored neurobiological mechanisms in cognitive functions and disorders using diffusion imaging.

Throughout these experiences, he was also working with Vesna to develop the technology that will be the base of Mint Labs.

Vesna Prchkovska is a Macedonian who finished 5-year engineering studies in computer science, informatics, and control systems at University Ss. Cyril and Methodius in Skopje before starting her PhD studies at Eindhoven University of Technology's Department of Biomedical Engineering's Biomedical Image Analysis group. After her PhD, she continued her work as a Marie Curie research fellow at various institutions: first at Computer Vision Research Group at Universiti Sains Malaysia, Penang, Malaysia where she developed new algorithms and techniques for brain imaging and studies; then at Neuroimmunology Group at IDIBAPS, Barcelona, where she studied functional and structural connectivity networks using various neuroimaging techniques and computer modeling to better understand the human brain connectome; lastly at the Department of Radiology of Massachusetts General Hospital of Harvard University where she explored the network and graph based theory applied to brain connectivity matrices from diffusion MRI and fMRI in healthy subjects and patients with neurodegenerative diseases, lastly, she returned to the Neuroimmunology Group at IDIBAPS, Barcelona, where she studied novel brain connectomics approaches in understanding the structure and function of the brain using the disconnection syndrome.

After these valuable experiences, they focused on developing the technology of Mint Labs in Barcelona starting in April 2013. Over time, they grew the company by hiring a business manager, Big Data Engineer, Scientific Engineer, Visualization Engineer, and Heads of Engineering and Neuroimaging, and are growing every day.

#### **b. Activities**

Mint Labs is a rapidly growing startup in healthcare informatics (IT) industry. The industry was born with the advancements in technology, to respond to the growing needs of healthcare companies. Their main aim is to support the companies, however, the way

they do business is very different than the traditional one. Thus, they are referred to as disruptive. They create, from scratch, new businesses with innovative ideas that lead to disruptive changes across value chains.

Mint Labs is one of these disruptive start-ups. Mint Labs offers a vital solution to researchers, doctors, clinical trial organizations, and pharmaceutical companies via its platform. The Mint Labs Platform is a cloud-based software that comprises various tools for the collection, management, analysis, storage, and sharing of imaging data. Now, focusing on brain MRIs, the platform will be able to accommodate PET and CT data in the near future. The company also has a desktop version for ease of use called Mojito.

Starting with data collection, researchers or doctors can upload their multimodal imaging data to the platform with drag & drop tools. The data is automatically de-identified regarding the sensitivity of the patient's medical information (protected health information) and is given an ID number. This is part of the HIPAA compliance of the platform that is semi-necessary, to be discussed further in detail. The data is then put into storage and is ready to be processed. A user then chooses the data they would like to perform analysis on and the type of analysis (morphology, volumetry, etc.). The platform processes the data, runs the analysis, and notifies the user once the analysis is completed. The user can then visualize the results in 3D and touchless motion and/or share the results with colleagues. Sharing of results can be performed within teams, centers or with external parties as others can be invited to the platform in any access level that the owner of the data desires.

The platform thus provides collection, analytics, and modeling pipelines to its users. The collection allows the standardization of data from multiple sources in addition to the collection of millions of brains from public data and clinical data (from hospitals and clinical trials). The platform may easily become a mutual meeting medium for public and private institutions from all around the world. With the aggregation of data, it is foreseen that patterns will be discovered much quicker and much more effectively, which will result



in a decrease in time span for early disease detection. Additionally, the analytics tools that assess brain morphology and function, and microstructural maps can be utilized as standard frameworks to evaluate the imaging data. Thus, Mint Labs believes that the platform is the perfect tool to support the research of the neurologists and other clinical players who have vast amounts of data but do not have the sophisticated tools to analyze their data. This results in them, in most cases personally, qualitatively analyzing thousands of images, which wastes precious time in clinical trial processes. The intuitive tools can be also employed to bolster research in biomarker development. Imaging biomarkers can be defined as biological features in medical imaging that are detectable, thus ease the objective diagnosis of diseases in diseases such as Alzheimer's Disease and Parkinson's Disease where early detection is crucial but very difficult. (Waterton, 2008) In addition to this, the touchless 3D visualization can be used by the scientific community for advanced interaction and exploration of imaging data. As mentioned earlier, with more than 160 thousand brain images available in the platform that is growing day by day, it can be an ideal space to discover patterns of brain morphology and tissue damage distribution. In time, with a larger collection of data, utilizing techniques such as deep learning and deep belief network (DBN), models can be built to train images and evaluate them against other images.

The end goal of Mint Labs is to become "the" milieu for all imaging data and other supporting data such as de-identified demographics, phenotype and bio specimen, to be able to fully understand the brain, and to support all research and clinical trials via its proprietary tools. This requires a collaboration between Mint Labs and its clients as the clients are the owners of the data and have deep understanding of the brain. Clients may have tools that can be added to the platform; which will be beneficial the scientific community as more people would be able to utilize them to advance their research. In addition to this, as clients will be experts in their fields, their feedback and ideas will be crucial for the advancement of the platform.

### **c. Competitors**

We can divide Mint Labs' competitors in five groups.

Firstly, the imaging informatics platforms provide open-sourced solutions for analysis of images. This is a newly developing market focused especially on research as it requires scientific knowledge to be utilized. One of the biggest names in this area is XNAT, a company from USA, providing an imaging informatics software platform with open-sourced tools targeted at imaging researchers as it is too complex, thus can be only utilized by experts. (XNAT, 2016) However, the platform is only focused on images, thus, is not flexible for other types of data. On top of that, the platform lacks advanced processing tools but it is possible to extend the processing pipelines with external additions. The second company is again from the US called Coins. It provides an online portal for archive imaging, reports, annotations, questionnaires, and other metadata however does not possess any processing capabilities, and is not user friendly. (Coins, 2016) Another important competitor to be mentioned is Flywheel.io as the software was created by researchers of Stanford University thus the reputation and recognition of the company is quite high. (Flywheel, 2016) It is the commercial version of the software created for the SciTran project. It is again an open-sourced scientific data management system to archive, organize, and share data. (Flywheel, 2016) It is focused on the scientific community only and does not provide any visualization or processing tools. Similar to what Stanford University did, University of California also supported its researchers to create LONI (Lab of Neuroimaging). (Loni, 2016) The software can carry out quantitative data analyses to create brain atlases for different segments with various tools it has under its umbrella. (Loni, 2016) Additionally, LONI is integrated with The Brain Mapping Siemens Sonata System. (Loni, 2016) Osirix, again a company from USA, has an advanced open-sourced PACS DICOM (the format of imaging taken by a number of the MRI machines) viewer, thus widely used in hospitals to view medical

images. (Osirix, 2016) However, it can incorporate all images, it is not brain specific, but it again lacks advanced processing tools. (Osirix, 2016) As PACS are local systems, this software also requires local installation. It has one big competitive advantage, the software is FDA cleared and CE class IIa labeled. (Osirix, 2016) NeuroVault, again a company born in the US, with support from Stanford University, provides a milieu for interactive visualization and publicly shared statistical maps and atlases from MRI and PET studies to improve meta-analyses performed on neuroimages. (NeuroVault, 2016) Neurosynth, another company from the USA offers a platform for large-scale synthesis of fMRI data, for meta-analyses, and for functional connectivity and co-activation maps. It additionally provides a number of advanced tools for image processing. (Neurosynth, 2016) The last company from the USA to be mentioned is called OpenfMRI. (OpenfMRI, 2016) It provides free and open sharing of all forms of neuroimaging data in small amounts, a framework for integrating data, and tools for data organization and processing. The last company to be stated within this group, interestingly from Germany, is called Aycan. It provides a remote multi-modal image viewer for iPad and has image manipulation capabilities however it not focused on neuroimages, thus does not have specific tools for brain. (Aycan, 2016)

To conclude, as can be seen, all these competitors were described as they provide similar tools or features but none does the same thing. They sometimes have competitive advantages over others such as support of universities or compliance or a focus on brain, etc., however, none provide as many features as even slightly close to Mint Labs.

The second group of competitors is composed of advanced neuroimaging providers which is a very niche market that offers tools developed by imaging experts for imaging experts. Interestingly, this group is not dominated by american companies. The first one, Olea Medical, is a French company that offers multimodal 3D visualization and processing in addition to perfusion imaging that requires local installation. (Olea Medical, 2016) The second company FEI is a dutch company focused on microscopy, providing

generic imaging and visualization; Its tools are very complex, developed by only for experts. (FEI, 2016) BrainInnovation, one of Mint Labs' biggest competitors in advanced neuroimaging is a company from the Netherlands focused on functional MRI processing. (BrainInnovation, 2016) Luckily for Mint Labs, the tools of the company are again only usable by experts in functional imaging. (BrainInnovation, 2016) SyntheticMR, a Swedish company, provides various editions of a software targeted for different groups. (SyntheticMR, 2016) Their aim is to provide a quicker MRI acquisition protocol and synthesize T1, T2 and FLAIR. The research edition of their viewer can measure Multiple Sclerosis (MS) lesion load, tumor volume, or ventricle volume; what Mint Labs' tools can also do. (SyntheticMR, 2016) CereScan, an American company, has a tool for advanced processing of a combination of SPECT and PET/CT images in particular; It is FDA approved. (CereScan, 2016) One of the most vicious competitors of Mint Labs, inviCRO is a company from the US that provides translational clinical and non-clinical imaging and processing in addition to data analytics and management. (inviCRO, 2016) On top of that, the tools are FDA Part 11 compliant. (inviCRO, 2016) BrainSuite is an American company that offers a collection of open source software tools that enable largely automated processing of magnetic resonance images (MRI). (BrainSuite, 2016) Additionally, the tools can visualize diffusion data and perform brain connectivity analysis. (BrainSuite, 2016) Brain Dynamics is a Spanish company that supplies computational methods of quantitative neuroimaging aimed at clinical trials such as data collection, data mining, and visualization. (Brain Dynamics, 2016) It can also characterize patient profiles using quantitative analysis of neuroimaging biomarkers. (Brain Dynamics, 2016) A US based company called Intererad provides various different software for advanced viewing, sharing, and data management such as InteleViewer, IntelePACS, Nuage. (Intelrad, 2016) They are all FDA approved, however, all of them are separate whereas they are all together on Mint Labs' platform. (Intelrad, 2016) NordicNeuroLab from Norway provides neuroimaging for fMRI and advanced MRI perfusion via various tools such as T1&T2 mapping, DTI, and perfusion; all tools are FDA

approved, CE marked. (NordicNeuroLAB, 2016) 3D-Doctor is again an American company that offers advanced 3D image modelling, processing, and visualization; their software is FDA cleared. (3D-Doctor, 2016). The last company to be stated is called Prism Clinical, again from the US. The company provides processing and viewing of fMRIs, DTIs, MRIs, ASLs, and DSC perfusion MR images via its tools that are FDA cleared. (Prism Clinical, 2016)

These advanced neuroimaging providers are mostly compliant with the regulations to work with pharmaceutical companies on clinical trials, however, they only provide tools that are similar to each other, and also similar to those provided by Mint Labs. Thus, it is very expensive for clinical trial stakeholders to license their tools and also license other softwares for their other needs.

The next group of competitors is comprised of cloud storage providers. This is a growing market but also a difficult market with tough competition. They can sometimes be integrated with Electronic Medical Records (EMRs) or via mobile. We will again observe a domination of companies from USA. To begin with, Calgary Scientific, from USA provides both 2D and MIP/MPR 3D interactive visualization in addition cloud storage, specifically for mobile devices. (Calgary Scientific, 2016) The company also has diagnostic tools based on viewing only and this is FDA approved and CE marked. (Calgary Scientific, 2016) Carestream Health, again an American company, offers a software called Vue Motion which is a HTML5 cloud based viewer without any processing algorithms. (Carestream, 2016) The software is available for a number of medical areas and in 150 countries around the world. (Carestream, 2016) MIM Software, again a company from US, offers two products, MobileMIM and MIMCloud for remote viewing of images from mobile devices. (MIM, 2016) However, as in the case of Carestream, it does not have any focus on brain. (MIM, 2016) The products only provide viewing and has no other algorithms. (MIM, 2016) A very important company to be mentioned is Dell's, thus from the US, Unified Clinical Archive system which offers archiving services to images

from different sources such as picture archiving and communication system (PACS), healthcare imaging services (HIS), vendor neutral archives (VNAs) and health information exchange system (HIE). (Dell, 2016) The unified clinical archive is ISO 13485:2003 certified. (Dell, 2016) Another competitor that must be mentioned is one of the leading companies in the industry, Merge. Merge was bought by IBM Watson and has over 30 billion images. (Merge, 2016) The reasoning behind this acquisition is that IBM aims to analyze Merge's image database with Watson's machine learning algorithms to reach new conclusions. (Merge, 2016) Merge provides archiving for images from radiology information systems (RISs), PACS, and computer aided diagnosis stream. (Merge, 2016) The software has FDA Class II medical device clearance and is CE marked. (Merge, 2016) Another big competitor is USA's giant operator AT&T's Medical Imaging and Information Management. (AT&T, 2016) It provides synaptic storage for PACS, RECs, and HIEs, and access to WADO. (AT&T, 2016) Additionally, the software has FDA clearance. (AT&T, 2016) Another company, again born in the USA, is called EMC. It provides a special infrastructure that supports the integration of PACS and VNA from various sources under the Dell umbrella. (EMC, 2016) Sectra, born in the US, offers various storing tools such as ECG, RIS, EMR, PACS, XDS in addition to proprietary data analysis tools and its FDA approval is pending. (Sectra, 2016) NetApp, operating in the USA, partnered up with BridgeHead Software, provides an advanced VNA called IronMountain with archiving, communication, and sharing capabilities. (NetApp, 2016) This software also protects and manages healthcare data. (NetApp, 2016) Hyland, a US based company, has a software called OnBase which functions as both a vendor neutral archive and a multi-vendor PACS system leveraging on enterprise content management (ECM) technologies. (OnBase, 2016) Novarad Healthcare IT and Imaging, an American company, offers a vendor neutral archive that can migrate all data to a central archive, replacing all PACS and CPACS with a customizable workflow module. It also functions in XDS format. (Novarad, 2016) Philips Healthcare & Hitachi partnership, based in the USA, provides a highly scalable and high-performance VNA

solution for PACS and image analysis. (Philips, 2016) Another company from the USA, DeJarnette also provides a VNA but with local, enterprise, or regional storage capabilities. (DeJarnette, 2016) Their software has a full-featured PACS migration toolkit, routing ability, CT workflow engine, and an integration engine for PACS, RIS, and HIS. (DeJarnette, 2016) The last american company to be mentioned is Box. Although it is a general file cloud storage platform like dropbox it can actually be connected with an enterprise solution. (Box, 2016) A Canadian company called Synaptic Medical has created a software called ClearCanvas that provides a zero-footprint software application organizing, storing, and distributing images that is also FDA cleared. (ClearCanvas, 2016) The last company to be stated is from UK, called 3Dnet. The company offers a fully integrated imaging system with management and visualization capabilities. It is scalable, and interoperable, and is ISO 27001 accredited. (3Dnet)

As in the case of imaging informatics platforms, all the competitors in cloud storage are doing somewhat the same thing but have some additional features. Some are compliant with FDA or ISO, which provides a huge advantage. However, they address all medical images and the whole market. They do not provide analytics, only storage. Thus, they only deliver one part of what Mint Labs can offer.

The fourth group, very similar to the cloud storage providers mentioned above, offer Vendor Neutral Archive (VNA) Systems. Most of the cloud providers offered their VNAs is cloud environment. The following companies offer local VNAs but cover an extensive market for enterprise solutions for image viewing and sharing. The first VNA provider was created by the collaboration of two US based companies, Acuo Tech and Lexmark Healthcare. They offer an enterprise based Vendor Neutral Archive incorporated with electronic health records; and it is FDA approved. (Lexmark, 2016) The second company McKesson Diagnostic Imaging (USA) has a very similar technology of enterprise imaging based on electronic health records, however it is HIPAA compliant and DIACAP cleared. (McKesson, 2016) A critical competitor to mention here is Siemens Healthcare, from

Germany, with its universal VNA and sharing platform called Syngo.share. (Siemens, 2016) Siemens' greatest competitive advantage stems from the fact that most imaging machines are Siemens. Mach7 Technologies, an American company also provides enterprise imaging VNA however, on top of that, it has a communication workflow engine with rapid migration and study split features. (Mach7, 2016) Cerner, a Canadian company, developed a software called CareAware Multimedia for multimedia management, and it can be integrated with electronic health records. (Cerner, 2016) CoActiv Medical from the USA has created a proprietary software for advanced PACS and RIS management and the technology is both FDA approved and HIPAA compliant. (CoActiv, 2016) Medisor Imaging, again an American company, also offers VNA and local storage services in addition to modality worklist services. (Medisor Imaging, 2016)

Vendor Neutral Archive providers, similar to the cloud storage providers, mostly only provide a means of storage. Some have a couple of additional features or analytics, however they all require a large number of other tools to be used together to conduct the same analyses a researcher can conduct with Mint Labs' platform. Their only competitive advantage comes from their compliance standards which makes them suitable to be used in clinical trials.

The last group of competitors to be mentioned are the imaging biomarker providers. These biomarkers are very crucial for the diagnosis of a number of diseases as they can be defined as a biological feature that can be detected in a medical image. (Prescott, 2013) With the rise in occurrence of diseases that are very hard to diagnose such as Alzheimer's Disease, Parkinson's Disease, and various types of cancer, these biomarkers' importance also increases. As Mint Labs' platform also uses various biomarkers for its diagnostic and analytic processing, these companies are key competitors. The first one to be mentioned is Quibim from Spain. It offers various biomarkers from morphology to tractography to cover from oncology to cardiovascular diseases. (Quibim, 2016) Another company icometrix, from Belgium, can conduct



various analyses such as thickness and perfusion and offers the ability to create standardized reports for diseases such as Multiple Sclerosis. (icometrix, 2016)

Additionally all tools are CE marked and ISO 13485 certified and are awaiting FDA clearance. (icometrix, 2016) Quantib, one of Mint Labs' biggest competitors in biomarkers is a company from the Netherlands offering CRO service for both MRI and CT scans covering neurovascular, musculoskeletal, abdominal, and lung structures. (Quantib, 2016)

It also has the capacity to support large-scale research. (Quantib, 2016) Pixyl is a French company extracting quantitative neuroimaging biomarkers for improved insight for clinical studies. (Pixyl, 2016) It has both local and web-based integration. (Pixyl, 2016) CorTechs Labs from the USA has created a software called Neuroquant which can perform quantitative MRI measurements and volumetric MRI processing. (CorTechs Labs, 2016) On top of that, the software is FDA cleared, CE marked, Health Canada licensed. (CorTechs Labs, 2016) Their compliance and focus on MRI makes them one of the biggest competitors' of Mint Labs. A company from Denmark called BrainReader has various biomarkers that can analyze images and carry out volumetric brain segmentations on a diverse database. (BrainReader, 2016) It's biomarkers are both FDA approved and CE marked. (BrainReader, 2016) CorticoMetrics is another american company that provides advanced neuroimaging data analysis software based on FreeSurfer that is focused on epilepsy, tumors, Alzheimer's Disease and Multiple Sclerosis and is FDA cleared. (CorticoMetrics, 2016) Regarding the company's focus on brain, FDA clearance, and FreeSurfer base, it's very similar to Mint Labs in analytics, thus is an important competitor. VolBrain was created by a collaboration between Spanish and French researchers. (VolBrain, 2016) The company only offers online MRI brain volumetry analysis, however, they work with a high number of institutions. (VolBrain, 2016) Imagilys, a belgian company, has proprietary tools for viewing and processing of brain images. (Imagilys, 2016) The tools can visualize, fuse,

and export multi-modal brain images from fMRI, Diffusion MRI, DSC & DCE Perfusion; and they are all ISO 13485 certified, CE marked, FDA approved, HIPAA compliant. (Imagilys, 2016) This places Imagilys high on the list of competitors as it offers advanced processing and visualization of multi-modal data and is compliant with all the regulations. inviCRO is a company from the US providing translational imaging capabilities for clinical imaging and clinical trials, for diagnosis, monitoring, and support purposes. (inviCRO, 2016) The company also provides proprietary tools for data analytics and management and these are FDA compliant. (inviCRO, 2016) With advanced algorithms similar to those of Mint Labs' and because the company is FDA compliant, inviCRO is again an important competitor. The last company, Brain Dynamics, is a Spanish company that provides computational methods of quantitative neuroimaging aimed at clinical trials. (Brain Dynamics, 2016)

Even though most of these imaging biomarker providers have very advanced and mostly proprietary tools for image processing, they only offer that whereas Mint Labs has similar biomarkers and these biomarkers only make up a small portion of the platform's value creation.

#### **d. Competitive Advantage**

Regarding the fact that the Mint Labs platform offers various services, thus responds to a number of the researchers' or doctors' needs, competitors of the company span across the industry, covering imaging informatics platforms, cloud storage providers, advanced neuroimaging providers, VNA vendors, and imaging biomarker providers, as mentioned earlier. However, none of the competitors offer as many features as Mint Labs does, as stated above for many cases. Imaging Informatics platforms such as XNAT offer open-sourced solutions and are intended only for expert researchers. Cloud storage providers such as CareStream and GE Health Cloud do not have a specific focus on imaging or brain but provide storage for all medical imaging and other data, but only offer cloud

services. Advanced neuroimaging providers such as Olea and BrainInnovation, in contrast to imaging informatics platforms, have advanced proprietary tools developed by imaging experts for imaging experts, and require high scientific and technological know-how to be handled properly. VNA systems such as Acuo and Siemens, like cloud providers, provide only a storage solution that is not intuitive. Imaging biomarker providers such as Quantib and NeuroQuant do offer access to advanced algorithms to carry out analysis using the imaging biomarkers, which is vital for the advancement of medical research, especially for diagnostic and monitoring purposes of CNS diseases. However, the handling of these biomarkers also require expert know-how if not provided on easy-to-use way such as on Mint Labs' platform. The competitors that are FDA compliant or CE marked have an advantage over Mint Labs as Mint Labs will be FDA compliant and CE marked by the end of 2017, which provides them a time-frame to grow with less competition.

Nevertheless, what Mint Labs offers is all of these critically important solutions on the same platform, in the most simplified way. It is not only intended for experts with coding know-how. On top of that, the researchers have access to both open-sourced imaging informatics and proprietary advanced imaging tools through a cloud-based platform (both storage and processing is carried out on the platform). It also supplies biomarkers for CNS diseases such as MS and AD. The number of tools and biomarkers the platform offers will increase over time as with collaborations, partnerships, and projects with research organizations and other companies rise, Mint Labs' tools and biomarkers will also increase in number as Mint Labs aims to incorporate their offerings to the platform.

Another factor to be addressed is Mint Labs' focus on neurodegenerative diseases. Most of the competitors have offerings corresponding to brain diseases but only a very small portion has a specialization on brain or MRI as in the case of Mint Labs. This supports the company's claim to become a gold standard for CNS diseases.

The table below shows some of the differences in offerings of the main competitors vs. Mint Labs’:

		Imaging Informatics Platforms	Cloud Storage Providers	Advanced Neuroimaging Platforms	Imaging Biomarker Providers	Mint Labs
		Lori, XNAT	MIM, CareStream	SyntheticMR, inviCRO	Cortechs, Quantib	
Data Aggregation	Imaging	Yes	Yes	Yes	No	Yes
	Other	No	No	No	No	Yes
Multi-modal Analytics	Brain	No	No	No	Yes	Yes
	General	No	No	Yes	Yes	Yes
Compliance		No	Yes	No	No	Yes

Table 1: Comparison between competitors and Mint Labs

#### e. Barriers of Entry to the Market

To demonstrate the sustainability of the competitive advantages of the company, it is crucial to state the barriers of entry to the market of advanced neuroimaging analytics and cloud platforms.

Firstly, Mint Labs has unique and proprietary data analytics tools that were developed over the years, starting at their PhD times, by the co-founders and were advanced even further by the experts in backend platform, big data, medical image analysis, and data visualization. Thus, the development of these tools or similar ones from scratch would

take years of hard work when the user base of Mint Labs will exponentially grow with clients from all over the world adapting to the platform.

Related to the mentioned strength, with the early adoption of Mint Labs platform, the Mint Labs team will make sure that the users are utilizing all the different functions of storage, analysis, and sharing the platform can offer. Hence, the clients will bolster themselves to use the platform for all imaging data related purposes which would create a lock-in effect throughout the industry. After this point is reached, it would be highly challenging for a new company to come in and convince all the synced users to change to using their system as those who leave would not be part of the community anymore.

Additionally, it is a must to state the high financial requirements of the research and development of such advanced platforms. Both for the launch and for all the improvements, it is crucial to find investors and receive grants. This is very difficult regarding the number of startups that are born every day with similar needs. The founders have to have both solid know-how and good persuasion/pitching skills.

To conclude, with a close to blue ocean market, Mint Labs is moving fast in this rapidly growing industry to capture as many users as it can to create a differentiated and advantageous society for its users by perfectly responding to their needs.

#### **f. Business Model**

The business model of the company will be examined using the business model canvas. The canvas was preferred as the method of analysis as it offers a structured way to dissect the components of the business model with emphasis on the strategic implications of each aspect. (Osterwalder, 2013) It is a framework that shows how the company creates value for itself and its stakeholders. (Blank, 2013) The parts of the business model canvas can be listed as: key partners, key activities, value propositions,

key resources, customer relationships, customer segments, channels, cost structure, and revenue streams, as seen below. (Osterwalder, 2013)

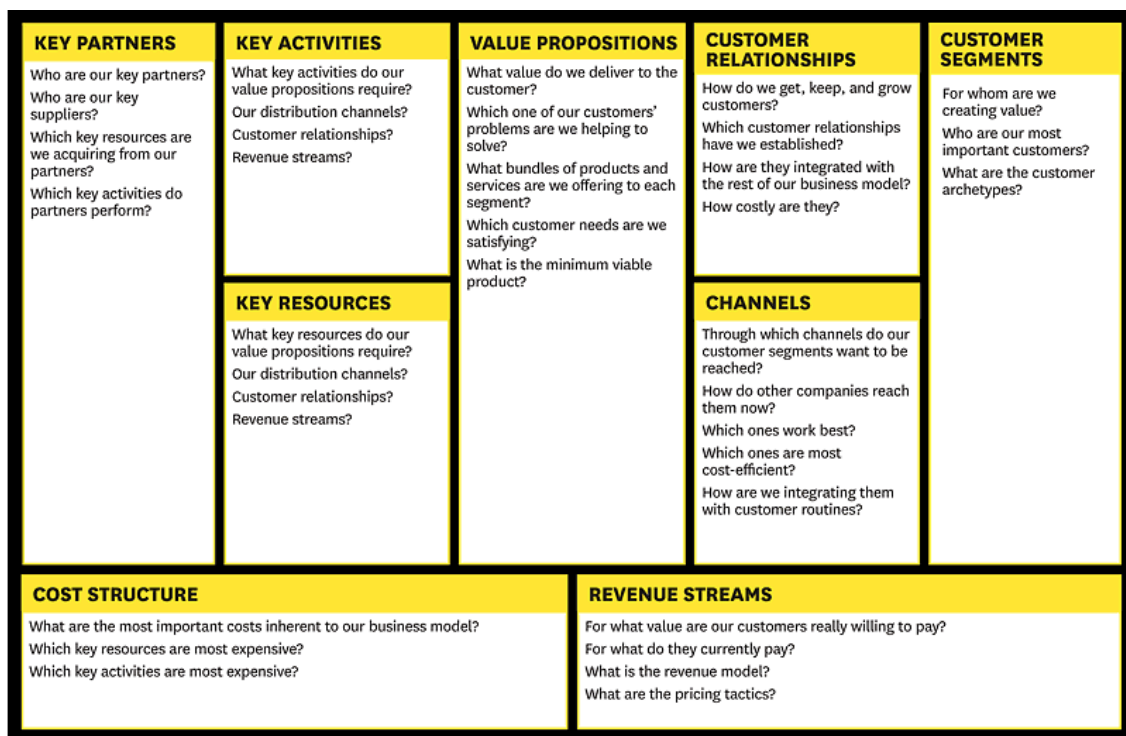


Chart 1: Business Model Canvas, (Osterwalder, 2013)

To begin with, the value proposition of the platform is built on solving the problems researchers and doctors face when handling data and carrying out analyses. First of all, on the data side, they have to manually integrate imaging data from different sources and lack the capabilities to integrate other types of data such as bio specimen with their imaging data. They manually de-identify data to respect the privacy of the patient health information, thus they spend a lot of valuable time for data management rather than conducting research. Additionally, unfortunately, they still lack easy ways to share data and still use CDs/USBs. On top of that, the datasets are growing with rising prevalence in diseases.

Secondly, on the analytics side, they lack computational tools for their analysis as these tools are mostly very expensive as they are licensed, thus, researchers and doctors are relentlessly inclined to carry out qualitative analyses. This might result in human error

and missing important predictors and makes it very difficult to capture patterns as it would take months even years for a researcher to analyze thousands of images by eye. Whereas same, even better results can be achieved using algorithms in a couple of hours. The lack of computational tools also makes it impossible to conduct reproducible research.

In response to these problems, Mint Labs' platform delivers value to researchers and doctors with its all-in-one-platform with cloud and desktop based access. Additionally, all data is automatically de-identified, standardized into categories, thus the privacy requirements are automatically followed. Moreover, advanced analysis can be performed with both proprietary tools and other open source tools which computes various measurements and brain mapping. As computational tools are used, all the results are reproducible, which enhances collaboration between researchers. All the results can be visualized in 3D and touchless and can be shared with anyone by providing them access to the platform according to the level of sharing the owner desires.

To conclude, the platform creates value for researchers by combining everything they need in a single milieu, thus solving all their issues at the same time. This saves them both money and time which allows them to focus on their research rather than dealing with time consuming data management or qualitative analyses.

Second, the customer segments of Mint Labs should be examined as the business model and the growth of the company is dependent on its customers. The first segment that is targeted is comprised of individual researchers and doctors handling a lot of MRI images for their studies or research. The next segment is composed of teams of doctors or researchers who utilize MRIs for their studies. The third segment that is reached via building relationships with the first two is consists of large research organizations and hospitals that house MRI machines and conduct research and treatment on thousands of patients. The fourth segment is comprised of top-notch research organizations and hospitals, similar to the third one, reached via building relationships with the first two

segments. The last segment is composed of Clinical Research Organizations (CROs) and pharmaceutical companies and Mint Labs aims to reach them through building relationships with the fourth segment, who are collaborators of CROs and pharmaceutical companies to conduct clinical research or trials.

Mint Labs utilizes various channels to reach its customer base; both face-to-face and online activities are carried out regularly. The face-to-face contact is crucial to meet potential clients (researchers, doctors, hospital representatives), establish leads and the team aims to build relationships to secure contracts. Additionally, this channel is crucial to meet investors interested in the platform and secure new investments. The initial meeting point is mostly at international medical symposiums and conferences or meetings arranged in relation to previous contact or word-of-mouth. These relationships can easily transform into partnerships as a mutually beneficial collaborative environment is built. Partners of the company are crucial as they prescribe the technology to their other collaborators and partners, which grows the customer base. Additionally, online marketing efforts are currently carried out through LinkedIn by specifically targeted ads, sharing regular updates on Twitter, monthly newsletter delivery to hundreds of contacts, and online demos. Efforts to raise recognition and reputation will be achieved by publishing white papers on the results accomplished through the use of the product on websites such as Researchgate and Academia where the targeted scientists who would benefit from the product can be reached. Lastly, the research and development team of the company regularly publishes articles in top scientific journals, which is essential to support the reputation.

As highlighted earlier, establishing relationships with all the different target segment groups is essential for the growth and future of the company. Thus, different segments receive different treatment, however, all are subject to some level of interaction.

Firstly, the individual users (researchers or doctors) are contacted regularly through automatic e-mails and are asked to provide any feedback they think might improve the



platform and receive monthly newsletters to get informed on the novelties in the platform and on the recent articles that might be interesting for them.

Secondly, teams of doctors and researchers also receive regular automated e-mails asking for feedback, however, they also receive personalized e-mails from the team to schedule meetings to discuss how their experience has been, if they have any feedback, if they need any support to carry out advanced analyses, etc. The reasoning behind this is that their satisfaction with the platform can lead to their research organizations or hospitals becoming subscribed clients. They also get monthly newsletters, same as in the case of individual users. The next segment, large research organizations and hospitals are regarded as potential research partners and collaborators thus they receive a much more personalized attention. They are regularly contacted via phone and/or e-mail to be asked for feedback and to be interacted to make sure that they are content with the features of the platform. They also receive the monthly newsletter.

The Mint Labs team focuses most of its attention on the second most important target segment that is composed of top-notch research organizations and hospitals. This is because this segment is the most crucial research partner of the company and the biggest prescriber of Mint Labs' platform, thus, they receive regular skype/call or face-to-face meeting requests from C level executives where their feedback is collected and additions, adjustments, and changes are realized according to their requests. They receive a monthly letter, however, they are always the first to know via e-mail the additions to the platform.

Both the large and the top-notch research organizations and hospitals can provide additional tools that may be added to the platform, thus, mutually beneficial relationships can be established. Mint Labs will be able to offer more tools to its clients and the organizations will receive a fee when the tool is utilized by other researchers, not to forget to mention how this collaboration will benefit the medical and scientific community by supporting the research activities.

The last segment comprised of Clinical Research Organizations and Pharmaceutical companies receive a similar treatment like the top-notch research organizations, however, as the objective of the company is to become the gold standard in clinical trials, this segment gets much more attention from the C level executives. Face-to-face meetings are preferred; regular Skype meetings are carried out. Their requests are always the top priority and the additions or changes are carried out as soon as possible.

The next key constituents of the business model are the key partners of the company. The most crucial one would be the cloud providers such as Google and Amazon Web Services as the platform is based on the cloud system. All the storage, processing, and other activities are done over the cloud thus it is the main source of computational resources.

The second group of key partners are composed of the clinical research partners of Mint Labs, the large and top-notch research organizations and hospitals. As mentioned earlier, Mint Labs collaborates with these stakeholders on special projects for certain diseases where Mint Labs provides data management, advanced imaging, computational neuroscience, and visualization tools and the collaborators provide data that grows the brain database of the platform, which is crucial for the company to reach its aim of becoming the biggest brain database in the world. It is also highly likely that the research organizations and top-notch hospitals have tools of their own which can be incorporated to the platform, which is beneficial for both the hospitals and Mint Labs. On top of that, Mint Labs and its clinical partners can develop tools together from scratch. All of these tools will provide revenue to both sides, additional recognition and reputation with their contribution to medicine and research community. Moreover, these clinical research partners can also be partners in applying to research grants; the grants are great extra revenue sources for both research and development and new hires.

Similar to the large and top-notch research organizations and hospitals, research foundations are also important partners. These foundations have both the influence

capability and the funds to change the rules or bring new standards to research. Thus, a possible collaboration with a large research foundation would put Mint Labs on the cover page of most of the research organizations, CROs, and pharmaceutical companies; the foundation will act as the prescriber of the platform.

Another group of possible partners to be discussed are the Clinical Research Organizations (CROs) and biotechnology companies. Again like in the case of research organizations, collaboration with this group of clients is crucial for both the reputation of the company and to secure the way leading to pharmaceutical companies. CROs are the main partner of pharmaceutical companies throughout their research and development processes, thus, tools and platforms used by the CROs would be more easily integrated into the pharmaceutical research and development value chain.

The last possible partnership would be between hardware and Vendor Neutral Archive (VNA) vendors and Mint Labs. This alliance would again be very favorable for Mint Labs as the platform would easily become the standard complementary tool to for imaging data management, processing and sharing to the machines that produce the images. Mint Labs' brain database will grow exponentially whereas the vendors would be able to provide complementary management, processing, and sharing capabilities with their machines, thus, additional value will be created for both companies.

To sum up, the potential partners are crucial for the business model's sustainability. The partners provide the imaging data, thus, render Mint Labs one step closer into being the biggest brain database in the world. Additionally, with the increase in the number of partners, both the business model and the value creation of the platform are validated. On top of that, the best way for Mint Labs to grow its customer and database is through its partners. The company relies mostly on word-of-mouth to build reputation, trustworthiness, and recognition. When the platform is used by top-notch research organizations, hospitals, and CROs, the name, activities, and the offerings of the platform will be shared with the community. On top of that, the partners are again pivotal

to reach the pharmaceutical companies. As the company also aims to become a standard support tool for clinical trials to accelerate the research and development process, it is paramount to build a secure bridge to build and establish relationships with the pharmaceutical companies. In this case, it is expected that the research organizations and CROs who are partners of pharmaceutical companies to provide this connection.

The next items of the business model can be referred to as key resources. The primary key resource that is also supplied from a third party is the cloud system. The company is using Google Cloud and Amazon Web Services for the cloud infrastructure of the platform where all the storage and processing is realized. The second set of key resources can be called the externally sourced tools that are utilized within the platform for various activities. They can be the basis of a feature or can be provided as open sourced tools via the platform. The platform's architecture is built with nginx, mongodb in Google Compute Engine. The analytics are developed using python and C/C++. Linux Container technology is also utilized for the development of various features. Additionally, Mint Labs' platform houses proprietary tools and features developed by the founders and the R&D engineers of the company. These tools' patents are filed, thus, their intellectual property rights will be protected very soon. These tools are essential for both the existence of the platform and for the analytical capabilities of the platform. Moreover, to validate the platform and its value creation, the fourth key resource is data. Public (from public organizations and hospitals) and/or private (from research institutions, hospitals, imaging centers) data (from third parties) has to be uploaded on the platform to demonstrate the abilities of the Mint Labs' platform. Lastly, another key resource to be mentioned are the employees of the company as what the company does is research and development intensive, the improvements on the platform and maintenance of the platform is crucial for the business; and all are done via specialists.

Furthermore, the key activities should be re-acknowledged as part of the business plan. Firstly, the platform offers simple data collection as researchers or doctors can upload hundreds or thousands of images from different sources with just drag-and-drop. The platform processes the data with its advanced data management capabilities, de-identifies, then standardizes and groups all the images. This processing makes the selection of data and analysis very easy as all the data are in the same place and in the same format. Moreover, the platform provides various sourced (open and closed) and proprietary tools built on state-of-the-art algorithms. Researchers and doctors can carry out a number of analyses using these tools and identify anomalies, changes, trends, etc. on their data. All of the analyzed brain images can be visualized in 3D with a software called BrainVis developed by Mint Labs that is incorporated into the platform. Finally, the sharing activity supports the collaboration between parties in research and clinical trials. All the users of the platform have the ability to share a link with another member of their team or center or with an external party to give access to their data and analysis at a previously defined level. The owner of the data can select a third party to also be an administrator, or be a collaborator, or be a viewer. This is a great feature for organizations with multiple teams or centers or organizations collaborating with external parties as it removes the hassle of sharing data via USBs/CDs and the necessity to run analyses locally. All parties can work on the data at the same time and render the platform the medium of studies.

Another critical part of the business models is the revenue model. It is based of Software as a Service or SaaS revenue model that is widely used by various start-ups and technological companies. Most innovative software companies use this model to deliver their services to their customers. Software as a Service model relies on a “pay-as-you-go” model where the customers pay according to how much they use the service. (Kepes, 2016) The model also includes the possibility of having subscribed clients and free users for certain cases. (Kepes, 2016) Most companies offer free trials to attract

customers and create a habit to convert them into paying clients or for public relations and marketing purposes. (Kepes, 2016) To be able to use a Software as a Service model, the company has to provide access via web where the software is administered from one location to a variety of users. (Kepes, 2016) Users do not have to do re-installations but the company carries out all the upgrades and maintenance work such as bug fixes on the software. (Kepes, 2016) Additionally, Application Programming Interfaces (APIs) are employed to integrate different pieces of the software that build the end product. (Kepes, 2016)

According to Kepes, a number of companies operating web-based or cloud-based technologies such as “vanilla” offerings or technologies with no competitive advantage, applications that provide a basis of communication with a third party, applications with high need for web or mobile accessibility, software responding to short-term need, and software with varying demand can utilize Software as a Service revenue model. (Kepes, 2016) Mint Labs’ Platform is under the category of applications with high need for web or mobile accessibility as the one of the most important value creations of the platform comes from the cloud base and another one comes from the sharing capabilities. Some of the most well-known companies utilizing Software as a Service revenue model are Google, Skype, Salesforce, LinkedIn, Spotify, Athenahealth, Box, Dropbox, (Helena, 2013; Bulger Partners 2014). One of the reasons behind choosing Software as a Service revenue model rather than a Licensing model is that studies and real-life examples have proved that companies operating with a Software as a Service revenue model achieve much higher growth and higher valuations in the long run. (Key, 2013) However, a crucial issue to be addressed here is the “long-run” effect. This can create difficulties for companies such as start-ups without access to liquidity as the company will make money after the “Saas Revenue Flywheel” kicks in over time, approximately in 3 to 4 years. (Key, 2013) This higher growth nevertheless results in both more sales and a much bigger customer base than it is possible for a licensing model. (Key, 2013) This is mostly

because the SaaS model makes it possible for the company to provide free trials, thus, it is easier to attract more people than one can with a paid licensing, where there is no turning back after a license is bought. The growth in customers is mostly achieved via targeted advertising. (Patel, 2015) The freemium customers can be transformed into subscribed users. (Patel, 2015) Additionally, the Software as a Service model creates much higher, 50% in his example, customer lifetime value than does licensing, as the company undertakes all maintenance, operations, customer service and such overhead costs. (Key, 2013) However, Mint Labs, foreseeing the advantages mentioned, chose a Software as a Service revenue model instead of licensing and closed deals with private investors and organizations from all around the world in exchange for shares or special projects and has applied to grants to not experience any liquidity issues until the company reaches the exponential revenue growth part of the projections.

Moreover, the Software as a Service revenue model is delivered via different packages containing certain amounts of cloud storage and analyses specifically designed for different target customer segments.

The first one that is still widely applied is the free trial or freemium where customers have access to a limited number of features, selected by the Mint Labs. Mint Labs' free trial includes only 10GB of storage and 20 analyses and expires in 3 months. Some other leading companies offering freemium services are Google (Gmail), LinkedIn, Spotify, Apple (Apple Music), Box, Dropbox, etc.

The second one is the pay-as-you-go clients who can be individual or small teams of researchers or doctors interested in using the service. They pay 50\$ for 10G of storage and 1 analysis. These users are mostly researchers handling a certain amount of data in organizations with limited funding, who have used the platform during the free trial process and have benefitted from it, thus decided to pay a small fee.

The third and fourth groups are called "Starters" and "Basics" respectively. They consist of teams within research centers with substantial funding where individual researchers

have already used the platform with free trial and were satisfied with the offerings. The starters pay \$500 per month for 50GB of storage and 10 analyses whereas basics pay \$1000 per month for 100GB and 30 analyses.

The next segment is referred to as “Standard”. This customer group are generally large university hospitals or research centers handling a high number of neuroimages on a daily basis for the research of a number of teams made up of a number of researchers or doctors who have previously utilized the platform and have appreciated the benefits of it. The standard package includes 1TB of storage and 175 analyses for \$5000 per month. As these institutions have big data clusters and a high number of patients, their gain from the platform is substantially high. Instead of separately paying for storage and analyses tools where analyses tools are mostly licensed, thus, very expensive, they just have to pay for the platform and infinite number of researchers or teams within the organization can utilize the service (within the storage and analysis limitation).

The sixth group of segments is referred to as “Premium”. These are very large, top-notch university hospitals and research organizations such as Harvard Medical School or Massachusetts General Hospital where the amount of imaging data and the number of patients is very high and a very large number of teams will be utilizing the platform to support and advance their research. In this case, custom packages are created according to the needs of the organizations; there may be emphasis on storage or emphasis on analyses, or both. The payment will again be on a monthly basis.

The last segment is called “Site”. These can again be top-notch research organizations or hospitals but they can also be Clinical Research Organizations (CROs) and pharmaceutical companies. Because of the size of the organization, they will be receiving a special customer service from Mint Labs where the employees or Mint Labs will assist the organization in the migration of data and setup of accounts for the researchers and/or doctors. The organization will pay a one-time-only setup fee and a



monthly subscription fee according to its custom packaging consisting of a certain amount of storage and analysis, where the focus can again be on either or both.

One last note, additional packages of storage or analysis or both will be available for all the segments mentioned above at any time to render the platform infinitely and instantly scalable for all users.

The company has additional sources of revenue that should be examined to see the whole picture. The first one are the private investors (individuals and organizations). Since the beginning of its operations, Mint Labs has been supported by various private investors and accelerator programs. Some of these private investors turned into advisors of the company regarding their experience. To support their stake in the success of the company, they have been very helpful and will continue to be very helpful in contacting and convincing key customers and closing deals. Both their testimonials and their financial/moral support is crucial for the company. Walter Gilbert, the founder of Biogen and Myriad Genetics, and Nobel laureate; Dr. Michael Fox, an assistant professor specialized in Neurology at Harvard Medical School and Beth Israel Deaconess Medical Center; Dr. Chris Llewellyn, a former surgeon is a partner at McKinsey & Company's London office where he is the head of Medical Products Practice in EMEA and a leader in the company's global Pharmaceutical Practice; to name a few of these key opinion leaders. On top of that, startup supporting programs such as Wayra Accelerator, NeuroLaunch, and Bayer Startup Accelerator. Additionally, the first seed round will be closed at the end of 2016 where €2.5 million will be raised, and €0.45million of that is already committed from various investors.

Moreover, another key revenue stream are the special projects with research institutions. When some hospitals or research organizations need a certain advanced analysis carried out for their dataset to reach certain conclusions, Mint Labs' R&D experts can perform these analyses for them and thus paid according to a special contract.

As stated earlier, one of the most critical activities of Mint Labs are its partnership with complementary companies or research organizations. In exchange of a mutual creation of a new tool or algorithm or the placement of a third party's tool or algorithm, Mint Labs gets an additional revenue (shared with the partner) every time the tool is used by a customer. The more vital or indispensable the tools are, the more will be the revenue. Thus, it is essential to find the best partner to have the highest return on investment (for research and development) for the tool.

The last revenue stream for the company to be stated is grants. As the company creates state-of-the-art and unique tools that are beneficial for the all the areas of medicine, science, and research that handle and utilize neuroimages, the company applies to national grants in Europe and USA (both public and private) and international grants with its new projects and new features. Mint Labs applies to some of these grants individually and to others with institutions or companies with whom the company collaborates. As scrutinized earlier, the company's partnership with others give incubate various algorithms for analysis and a number of imaging biomarkers that are crucial for the early diagnosis of central nervous system (CNS) diseases. As all these projects' biggest cost is the research and development, thus the man-hours spent, the grants are mostly utilized for salaries. However, as additional revenue streams, they can also be very conveniently utilized for PR and marketing activities.

As the last part of the business model canvas, the costs of the company and their structure will be examined. The foremost important cost stems from the personnel salaries, a key resource, as the what the company does is very research and development intensive. For new developments, for improvements, and for maintenance of the platform, highly qualified and specialized engineers were hired. Additional engineers are necessary to advance the platform to the next level such as adding new tools, new biomarkers or making the platform compliant with FDA regulations, or to render the platform ready to incorporate CT and PET images as it does for MRI images.

As can be expected, the salaries of such engineers are very high. The second cost to be pointed out is the cloud computing costs for storage and processing. As the platform handles sensitive private health information (PHI) and neuro images, to make sure that the platform and the privacy of PHI and images are not breached, the company uses mainly Google Cloud and additionally Amazon Web Services, the two biggest names, for its cloud needs. With the increase in the number images and analyses carried out that is growing day by day, the cloud costs rise, especially for the processing. As this is a key resource and the company has to partner with a top-notch cloud provider to satisfy its requirements to be HIPAA compliant (and FDA compliant in the near future), this cost will continue to increase with the growing number of customers, however, it is expected that the rise in revenues will be much greater than the rise in costs.

The last cost to be examined is linked to its PR and marketing & sales activities. The company has begun to execute marketing and public relations related activities within the last couple of months. Since its existence, Mint Labs relied on its advisors' support, its face-to-face contact with researchers and doctors at medical conferences and symposiums worldwide (focused on central nervous system diseases), and the founders' network to grow its customer base. However, the company has reached a point where, now, to jump onto the exponential growth phase of the projections curve, intensive marketing and public relations activities has to be carried out. Starting with hiring personnel to specialize in these marketing and public relations efforts in addition to customer relationship management, the total cost of employees will rise. Additionally, various online and offline means will be utilized to reach more customers. First focusing on LinkedIn Ads and Google Ads, moving onto Facebook, various social media channels' specialized algorithms will be utilized to reach the most important targeted customer segments. Moreover, the executives of Mint Labs will continue to attend more and more medical conferences and startup conventions to meet new customers, partners, and investors from all around the world. These conferences are a perfect way to perform

public relations activities as the recognition and the reputation of the company rises when it is invited to these events. The travel expenses for the events, nevertheless, sum up to big amounts considering how many has to attended to not miss out on opportunities.

On top of that, by partnering up with other companies and leading research organizations around the world, the reputation of the company is grown with word-of-mouth within the medical and pharmaceutical communities. This is crucial to find new lead and close deals as trustworthiness of their is pivotal for the top-notch research organizations and hospitals worldwide.

## **V. HYPOTHESIS**

The hypothesis of the project is based on the information accumulated above from research, industry analysis, and the examination of Mint Labs and the company's business model using the business model canvas.

The argument is that Mint Labs' business model is valid and the company will thus reach the clinical trial stakeholders who would benefit from the company's product, the platform, as the platform's tools and features will change how the data is managed, analyzed, shared, visualized during the clinical trial phases and on top of that, how the patients are selected. This is because the platform will automatize the steps of the process that are currently done manually. The algorithms will be able to identify trends and changes and draw conclusions from thousands of neuro images that are normally analyzed subjectively via observation by doctors which takes months if not years, thus, using the platform would save substantial time and cost to the stakeholders of the clinical trials.

Additionally, the platform's advanced analytics and imaging biomarkers can be used for early and correct diagnosis of critical diseases and their efficient monitoring, which is again crucial for the discovery and development of new treatments for diseases such as

central nervous system diseases where diagnosis of patients takes years and by then patients are at advanced phases of the disease, thus, even slightest improvements in their health conditions is near to impossible.

Consequently, Mint Labs' platform would have a great impact on the healthcare industry, thus, its effect can also be referred to as a disruption for the clinical trial processes.

## **VI. VALIDATION**

To validate the hypothesis mentioned above on the validity of the business model of Mint Labs and its destructive effect, as in the case of similar companies in the industry, on the pharmaceutical companies, interviews were conducted with various experts in the healthcare industry spanning across sectors.

The first interview was conducted with the CEO of Cyntegrity, Dr. Artem Andrianov. Cyntegrity offers customized solutions for different clinical trials to manage the risks via tools based on the data accumulated during trials to predict errors in the study, do necessary adjustments, and control results. (Cyntegrity, 2016) He is the CEO of the company responsible for the representation of the company in medical conferences and symposiums all around the world,

the data management technology itself, and the management of the company.

Dr. Andrianov was first asked if the Software as a Service model is logical for Mint Labs or should the company focus on transitioning all its customers into subscribed clients. He stated that the company should always separate academia and commercial clients. Customers from the academia would benefit from the free trials as this would support their research. He recommended that Mint Labs should provide special rates to academia to bolster the word-of-mouth within the community. He added that the free trial is the perfect way to acquire customers to create awareness and trust and the more trustworthy the company becomes, the more chances will there be to close deals.

Secondly, he was asked, regarding his own experience at CynTEGRITY, what would be necessary for Mint Labs to start working with clinical trial stakeholders. He stated that the first requirement would be to be ready for an audit by a pharmaceutical company, to have validations, everything documented and planned on how the software is tested, on scripts, on features, responses, to have standard operating procedures (SOPs), to build both a backtracking system and a change management & request tracking system. He stated that directly reaching pharmaceutical companies would be very difficult as they do not like sharing, prefer isolation for now. However, he recommended Mint Labs to have a solid positioning on both LinkedIn and Twitter to show how innovative the company is. He added that the company should also use traditional ways such as white papers and publications to reach researchers. He also stated that the newsletter of the company should have a more holistic view, involve competitors, videos, webinars, articles, news on new regulations, changes in the industry, links summaries, mind maps, opinions, etc. and limited info on the novelties of the platform so that the company can fully establish its positioning as a scientific company. He also recommended that more research should be supported for free so that these investigators can talk about how Mint Labs has aided and advanced their research in medical conferences and symposiums to increase word-of-mouth to reach the pharmaceutical stakeholders. He said the company should involve key opinion leaders from the industry that have utilized the platform in PR activities such as webinars where specific topics are addressed and Mint Labs' benefits are showcased. He lastly stated that it might be interesting for professors to use the visualization tools in classes with their students in medical school to show how critical diseases such as Alzheimer's and Multiple Sclerosis looks like in 3D; and the company can also post these 3D maps on its website to be downloaded for free for PR purposes.

The second interview was conducted with Trifermed CBDO's Vice President of Business Development Dr. Clara Nascimento. She is a Brazilian biologist with more than 10 years

of experience in academic research and in healthcare startup companies. (Trifermed, 2016) She is focused on business development for pharmaceutical and life sciences companies especially in Latin America. (Trifermed, 2016) Trifermed CBDO is the first Contract Business Development Organization in the world founded in 2002. (Trifermed, 2016) The company offers support for finding business development opportunities to companies within the healthcare industry such as pharmaceutical companies, biotechnology companies and medical technology companies. (Trifermed, 2016)

The first question Dr. Nascimento was asked was on the Software as a Service revenue model, whether it was suitable for Mint Labs. She believed that the model was very useful for Mint Labs' case as the company could offer both pay-as-you-go and subscription based on the needs of different client groups. On one hand pay-as-you-go is necessary to address the needs of research groups with less funds, less analysis and less usage. On the other hand, she thought that subscription was easier for big hospitals or companies as they have high amounts of data. A high number of analyses will be conducted thus it would be very difficult for researchers or doctors to get approval for every payment whereas a flat fee would include all. She added that different rates should be provided for companies of different size depending on an estimation of their needs.

Secondly, the company's roadmap to clinical trials was questioned. Dr. Nascimento was asked if the platform would be beneficial for clinical trial stakeholders and whether referrals from the research community would help the company reach these stakeholders. She believed that the platform would be very useful for the clinical trial market as they need collaborative environments where it is easy to access results from different parts of the world to compare and discuss results. She added that these stakeholders are much more willing to change than the researchers as they are dealing with very large amounts of data and solutions such as Mint Labs' platform are solving their problems. She felt that the referrals would be a good start to reach the clinical trial stakeholders as they create recognition for the company, however she believed that the

clinical trial was too big to not actively act on. She recommended that Mint Labs shouldn't only rely on word-of-mouth but to participate to congresses and fairs, to invest in marketing and people, be in active relationship with CROs and big pharma companies; and to be compliant with FDA as soon as possible. She also commented that it was crucial to show the advantages of the company, how using the platform would save time and boost the researchers' activities. She believed that if one company would adopt the platform, others would follow so it is worth the investment of people and money. She recommended the company to showcase its big data features as it is very hip now and data gathering and comparing is very valuable for clinical trial stakeholders.

Third, she was asked if she thought other companies in the healthcare industry would be interested in partnering up with Mint Labs. She stated that companies would be willing to partner up if they are small, in the growing stage, where the partnership will help them grow. Or companies in the same growth stage as Mint Labs can partner with the company if they would benefit from the merger as innovative ideas can be turned into products with the funds of the two companies combined. However, if it is a big company, then as they would have a big share of the market, they would not want to partner with Mint Labs to make sure that they do not lose any sales. She lastly added that the company can partner with other companies who have tools that are complementary to the features of the Mint Labs platform as this would improve the platform which would push big clinical trial stakeholders to pay to use the platform.

Finally, she finished with a note from her observations that the company should grow horizontally to add more features on different parts of the body as this would increase the value added of the platform for big companies. Mint Labs' relationship with the clinical trial stakeholders will deepen as if they are using it for the brain, they can easily use the platform for other trials, thus, the company can grow very fast. The stakeholders would benefit from having one platform or one system for all of their trials.



The next interview was conducted with Dr. Harald Jainta of Desitin Arzneimittel GmbH. Desitin is a company focused on Central Nervous System (CNS) diseases to improve pharmacotherapy through collaborations and partnerships, especially for epilepsy and Parkinson's Disease. (Desitin, 2016) He is the head of business development, responsible from finding new CNS pharmaceuticals or medical devices for co-development, licensing, co-marketing purposes to grow in Europe. (Desitin, 2016)

Dr. Jainta was firstly asked, similar to Dr. Andrianov and Dr. Nascimento, if he thought the clinical trial stakeholders would be interested in Mint Labs' platform regarding his experience working and partnering with pharmaceutical companies. He responded that he believed both the contract research organizations (CROs) and the big hospitals generating a lot of images would be very interested in the software. He added that pharmaceutical companies would probably not be directly interested as companies such as Biogen and Pfizer who are carrying out research and development activities have their own established systems thus it is unlikely for them to change. He recommended that Mint Labs should direct a clear message to the researchers that the platform links the generated images and their processing as now, this is done very primitively. He stated that Mint Labs should emphasize that the platform would connect images and medicine with an automated system via marketing efforts focused on the message of bringing people with same goal together for better diagnosis via imaging. He finished by warning that the company might experience problems with hospitals as the reimbursement processes are very slow and public health systems are very reluctant to add costs in Europe, however, the company should not experience such problems with CROs as their trials are sponsored by pharmaceutical companies with large funds.

Secondly, because of Desitin's focus in central nervous system diseases, its pharmaceutical activities, and its inclination to form collaborations and partnerships, Dr. Jainta was asked if Desitin would like to collaborate with Mint Labs, if he thinks a collaboration would create value. He said that the company needed support for its

research on epilepsy regarding the difficulties in diagnosis and prognosis with MRI images and thought that Mint Labs' analytics and biomarkers may be helpful for the advancement of these processes. On top of that, he added that a number of CROs in Germany would be very interested in Mint Labs' platform as Germany has a high number of clinical trials and pharmaceutical development in work in progress. He recommended Mint Labs to show how the algorithms of the platform can extract very useful and valuable information from the neuroimages as neuroimaging is very fashionable right now. According to him, this is because there is no single neurological disease that can be fully healed, they can only be slowed down; and to slow them down, early diagnosis is crucial, where neuroimages can make a huge difference.

The next interview was conducted with Dr. Enric Gibert who is the CEO of Pharmacelera. Pharmacelera is a company offering solutions to accelerate the drug discovery process with its computer aided drug design platform for the early stages of the pharmaceutical research. (Pharmacelera, 2016) Dr. Gibert is responsible from designing the computer aided drug technologies such as the ligand-based virtual screening tool and the 3D quantitative structure-activity relationship tool. (Pharmacelera, 2016) Pharmacelera's platform also targets the clinical trial stakeholders; their technology is to accelerate the phase 0 of the clinical trials where the candidate molecules are discovered; however, Mint Labs and Pharmacelera target the same stakeholders with the same motivation.

Dr. Gibert was first asked, same as other interviewed experts, if he thought the Software as a Service (SaaS) revenue model was suitable for Mint Labs. He answered that as the research groups, institutions, and public organizations who would benefit from the platform's offerings do not have access to enough funds, thus, they would be very content to use a "pay-as-you-go" service. On the other hand, he added that the CROs have enormous funds from pharmaceutical companies, thus, Mint Labs should also focus on CROs, however, as compliance can be a potential barrier, he emphasized the importance of advancing the privacy features.

Second, regarding Dr. Gibert's experience with clinical trial stakeholders, he was asked if word-of-mouth from researchers was a good way to reach them and what other ways would be advantageous for Mint Labs. He firstly addressed the point of investment requirements. He thought that the company would probably need more private investors' support to advance to reach the clinical trial stakeholders, thus, he recommended Mint Labs to establish a direct communication line with investors to exchange information. On top of that, he thought that the people of the company are key to reach these stakeholders so when attending conferences or events, the executives of Mint Labs should look beyond investors or clients to find candidates to recruit to the company. He also stated that customer relationship management is crucial to keep current customers happy, which is very important to develop the word-of mouth. He recommended regular newsletters, meetings (especially face-to-face), and more free services to some target groups such as researchers in exchange of publications or referencing to support the company's reputation. He also said that grants such as H2020 where the company can collaborate with some of the clinical trial stakeholders, such as CROs as they are more open than pharmaceutical companies, would create both a revenue stream and a very influential network.

Lastly, Dr. Gibert was asked with which partnerships Mint Labs would create the highest value. He stated that in two cases, the company would benefit from partnerships. First, in projects where the collaboration of two parties would result in opening new business units, thus, Mint Labs would have access to know how of third parties to have the opportunity to grow in new areas that are not directly related to core activities of the company. The second case would be to partner with customers to create additional value beyond the value created with the service itself by exchanging information (such as data) to come to new conclusions or develop new algorithms, etc. He finished by emphasizing that Mint Labs should watch out to not be a weak party in a small consortium as this would result in the company ending up doing all the work without benefitting from it.

Furthermore, Johnson & Johnson Turkey's CEO Ozgur Tomruk was interviewed to have more insight on how the pharmaceutical companies viewed technologies provided by companies such as Mint Labs. Johnson & Johnson is the world's largest drug and biotech company in terms of profits, assets, and market value. (Chen, 2015) Mr. Tomruk has vast experience in pharma and medical devices.

He was first asked if he thought the pharmaceutical industry would experience any changes or disruptions with the technologies of Mint Labs or similar companies. He answered by stating that these companies can sometimes be partners but sometimes be competitors of the pharmaceutical industry. However, there is a significant unmet need within the pharmaceutical industry regarding the incurable diseases, thus, there are various partnerships and collaborations going on to find promising treatments. He stated that Johnson & Johnson supports various companies (first financially) to advance their research, and if the technology succeeds, these companies are bought by J&J. Thus, he believed that the companies would create additional value for the pharmaceutical companies but would not be certainly disruptive.

Secondly, Mr. Tomruk was asked what was the best way to reach the pharmaceutical companies. He stated that the first way would be to participate in medical symposiums and conferences to present the platform. On top of that, he recommended Mint Labs to communicate the working principles and benefits of the platform with solid proofs such as the changes in the results of clinical studies when using Mint Labs' platform and when following conventional methods, percentage changes in error, percentage of improvement in efficiency, etc. He added that this is crucial as there are thousands of products and softwares claiming similar benefits, thus, the company should utilize these results to be convincing. He said that Mint Labs needs a good sales team with persuasion skills and high premiums to be able to reach this small target segment. He lastly recommended to also focus efforts on partnering up with hardware vendors such as GE to reach a wider network in the near future.

The next interview was conducted with Mrs. Deniz Akdemir from IMS Health Turkey. IMS Health is world's leading information, technology, and services company for the healthcare industry with access to hundred millions of patients' health data. (Tanner, 2014) Mrs. Akdemir's focus is on commercial and market strategies of pharmaceutical companies.

She was first asked if she thought companies such as Mint Labs would disrupt the pharmaceutical value chain with their advanced technologies and if pharmaceutical industry would outsource more of its activities. She believed that pharmaceutical companies would be willing to make use of this technology for their clinical studies and future solutions for patients. However, she was not sure whether this kind of technology or similar ones would evolve through outsourcing or acquisitions as she thought that big pharma giants would be willing to own the technology instead of outsourcing their activities because personalized healthcare is becoming a more and more popular subject and because it is really important to improve patient outcomes and beat competition in this context. She thought that the value chain of pharma companies and therefore healthcare market itself will be transformed although it will take couple of more years in developed markets. It will highly likely take-off with more burning diseases such as MS, Alzheimer's disease and cancer, which is a good point for Mint Labs as the company's focus in on CNS diseases.

Secondly, she was asked if she believed pharmaceutical or biotech companies would be interested in partnering with Mint Labs, whether this partnership would create value for the clinical trials, and what changes should be realized to come into their radar. She thought that pharma and biotech companies would be interested in partnering up with Mint Labs as imaging has become more crucial and companies that are especially not in this area would be inclined to collaborate with Mint Labs. She stated that currently, the biggest unmet need for neurologic diseases (and also for cancers) is to find the right targeted therapy for the specific patient as each patient's need is different. Therefore, she

thought that the company could create value in clinical trials. In addition, she believed that this technology would also change the current practice of physicians and that is where she thought that this technology would transform the status quo in current neurology area. Moreover, she proposed some actions to be in the radar of pharmaceutical companies: to collaborate with leading international and local authorities (leading neuroscience physician associations, big hospitals, leading key opinion leaders); to educate physicians to support research on this technology; to generate more and more outcomes and results to show that this technology improves patient outcomes and (if possible) more cost benefits in the value chain; to close partnerships with leading patient associations and physicians, to share personal patient stories and use them in Mint Labs' advertising on social media and international networking meetings/conferences; to be more tactical and provide Mint Labs' solution for free for more cases for a higher number of initial deals to increase penetration of this technology; to partner with leading high-tech giants (Google, Apple) which might change the outlook of the company and attract more pharma companies as in the case of Foundation Medicine that is focused on DNA sequencing who has got the support from Google and Bill Gates and then Roche Pharmaceuticals.

The last interview was conducted with Mint Labs' CEO Dr. Paulo Rodrigues to see his point of view on the company's future and focus and to discuss the experts' views on the company.

First, he was asked why the company chose a Software as a Service revenue model. He stated that this stemmed from the way the software is delivered, as it is on the cloud, not installed. He added that licensing would require high investments from clients, specialists or hospitals but with SaaS they can use as much as they need to, prices are fixed, thus it is very transparent and fair and it is much easier for clients to start using it with lower barriers of entry.

Secondly, he was asked if he believed technologies of companies such as Mint Labs will disrupt the value chain of pharmaceutical and biotech industries. He stated that in some aspects this will occur as the way these technologies assess the efficiency of clinical trials such as in stratification of patients, optimizing which patients should enroll in clinical trials will lower both cost and time. He supported this argument by providing an example and said there are 15 drugs in the Multiple Sclerosis market and several courses of therapies but it is a very long process to find the therapy that best fits the patients as it is a trial and error process, thus more personalized therapies are needed, where acceleration of development of treatments is key.

Third, Mint Labs' reliance on word-of-mouth to reach clinical trial stakeholders was questioned as a number of experts from the industry, as seen above, recommended specialized focus on marketing and other activities to reach the CROs especially as most of them believed that CROs would be more interested in the platform than pharmaceutical companies. He agreed that CROs would probably be more interested in the product than pharmaceutical companies and stated that Mint Labs should be more active with marketing and communication targeted at CROs but added that the company needs more people to do that. He added that the company has to become FDA part 11 compliant and ISO certified to work with CROs and that is why this is on the roadmap but not happening now. Nevertheless, he finished by stating that working with researchers is crucial to advance the reputation of the company to provide proof on the benefits of the platform.

Lastly, regarding the recommendations of some of the experts, he was asked if he would like to advance the platform to incorporate more body parts. He expressed that this is actually on the roadmap of the company as one of the future goals of the company however this can render the company very similar to competitors as the company would lose its competitive advantage of being brain focused. He added that this is very possible as with more people with PhDs in other parts of the body, tools and algorithms specific

to those parts can be created. These people would have the information and expertise now missing to develop the analytics and plan how to reach the targeted segments. He said that the new analytics would require the most time but data management and visualization would be very similar. He finally added that this would also be possible with collaborations when clients or partners add their already developed algorithms and tools on different parts of the body or on different diseases to the platform where they use the platform as a milieu to share this tool with the scientific and medical community.

## **VII. RECOMMENDATIONS**

The recommendations for the advancement of the business model and for the roadmap of the company are based on the recommendations of the experts, the literature review on the industry and similar companies, and observations.

First of all, the company should continue its focus on researchers to create word-of-mouth and make sure that more researchers have free access to the platform so that the recognition of the company can grow within the scientific community. On top of that, these free trials should be in exchange of some referencing or showcasing of the benefits and results achieved though using Mint Labs' platform at scientific conferences or symposiums to reach even more potential customers with advanced word-of-mouth. More collaborations with various stakeholders in the industry including doctors (neuroscientists and neurosurgeons), big hospitals, research centers, etc. should continue at higher speeds however, the users should be educated by Mint Labs to achieve the highest value creation.

Additionally, the company should dedicate man hours to become compliant with FDA and to acquire ISO certifications as soon as possible to work with Contract Research Organizations (CROs) as soon as possible as all the experts agree that the clinical trial stakeholder that would most benefit from the platform and would most be willing to partner with Mint Labs would be the CROs. Thus, standard operating procedures (SOPs)



should be prepared, backtracking, change management, and request tracking systems should be built into the platform.

Moreover, Mint Labs should hire marketing and sales experts to boost its marketing and PR efforts through primarily LinkedIn and Twitter to reach the targeted niche customers. The benefits of the platform have to be perfectly communicated with used cases, proofs, etc. where processes such as de-identification, extraction of information or trends via neuroimages should be shown. These proofs should show the percentage changes in error, improvements in efficiency, cost and time savings, etc. when compared to the traditional methods. The platform's collaborative environment should also be described to render it a milieu of meeting for researchers and doctors partnering on studies, trials, etc. Newsletters, webinars, demo videos, testimonials should be optimized and always widely shared. Nevertheless, the conventional methods such as white papers and publications are also significant for these customers, thus, research focus should not be lost. The company has to involve more and more key opinion leaders who explain the benefits of the platform to the community to support the sales activities and reputation of the company. The company also has to participate to more medical symposiums and conferences as both experts and the CEO view it as one of the best ways to meet potential clients, partners, and investors. Additionally, it is crucial for Mint Labs to establish a customer relationship management system to have high customer satisfaction rates to keep the number of active users (among all registered users) very high to solve a current problem.

Another point that was addressed by one of the experts was the increasing investment requirements of the company where establishing long-lasting relationships with the current investors would be very helpful for getting support from others.

It might also be in favor of Mint Labs to share the platform for free with professors in medical school for them to share it with their students, who will most likely be future clients of Mint Labs, for them to meet the platform and know about its capabilities, where

the 3D visualization of diseases that are very hard to diagnose would be crucial for these professors.

One of the experts suggested different pricing for different segments, which can be beneficial regarding the differences in their needs and to be more fair, which is one of the goals of the company.

Regarding the growth of the company thus its needs on a daily basis, as mentioned earlier, both R&D engineers and marketing & sales experts with background in pharmaceuticals or biotech should be hired.

On top of that, the company should continue to apply to grants all over EU and in the US to get additional funding that would be very useful to hire more people to advance the platform and add new tools, which is crucial for the company.

The company can also try to partner up with hardware vendors such as GE, Siemens, or Philips to automatically reach a high number of imaging experts, doctors, and researchers as the platform would come as a complimentary service to the regular users of the imaging machines. This would increase the number of images on the platform to millions very quickly which would bolster the company's goal and efforts to become the biggest brain database and to establish machine learning algorithms.

The company can also partner up with tech giants such as Google or Apple to create a new, more widely available tool which would maximize the recognition of the company and attract attention from all targeted segments.

A last recommendation from some of experts which was backed up by the CEO is to expand the platform into covering more parts of the body with more tools and more analytics. However, to accomplish this, more R&D engineers and marketing & sales personnel has to be hired to incorporate new tools to the platform and to market them to the right segments in the most suitable way. A key point here would be to partner with

clients or research organizations to have access to their know-how to develop tools or to share their tools via the platform.

To conclude, the objectives of Mint Labs are realizable if the company follows the recommendations of the experts to advance its marketing & sales activities, to optimize its revenue model, to focus on CROs, and to partner up with more organizations for mutually beneficial projects.

## VIII. REFERENCES

- 3D-Doctor. (2016). Main page. Retrieved from: <http://www.ablesw.com/3d-doctor/>
- 3Dnet. (2016). Main page. Retrieved from: <https://www.3dnetmedical.com/public/>
- Alzheimer's Association. (2016). Diagnosis of Alzheimer's Disease and Dementia. Retrieved from: [http://www.alz.org/alzheimers\\_disease\\_diagnosis.asp](http://www.alz.org/alzheimers_disease_diagnosis.asp)
- ASPE. (2014, July 25). Examination of Clinical Trial Costs and Barriers for Drug Development. Retrieved from: <https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development>
- AT&T. (2016). Medical Imaging and Information Management. Retrieved from: [https://www.synaptic.att.com/clouduser/html/productdetail/Medical\\_Imaging\\_and\\_Information\\_Management.htm](https://www.synaptic.att.com/clouduser/html/productdetail/Medical_Imaging_and_Information_Management.htm)
- Aycan. (2016). Main page. Retrieved from: <http://www.aycan.com>
- AZ. (2016). World Alzheimer Report 2015. Retrieved from: <http://www.worldalzreport2015.org>
- Blank, S. (2013, May). Why the Lean Start-up Changes Everything. Retrieved from: <https://hbr.org/2013/05/why-the-lean-start-up-changes-everything>
- Box. (2016). Healthcare. <https://www.box.com/industries/healthcare>
- Brain Dynamics. (2016). Quantitative Neuroimaging. Retrieved from: <http://www.brain-dynamics.es/index.php/en/>
- BrainInnovation. (2016). Main page. Retrieved from: <http://www.brainvoyager.com>
- Brainreader. (2016). Neuroreader. Retrieved from: <http://brainreader.net/p/product/neuroreader>
- BrainSuite. (2016). Main page. Retrieved from: <http://brainsuite.org>
- Bulger Partners. (2016). 5 SaaS Revenue Models You Should Know About. Retrieved from: <http://bulgerpartners.com/5-saas-revenue-models/>
- Calgary Scientific. (2016). Main page. Retrieved from: <http://www.calgaryscientific.com>
- Carestream. (2016). Main page. Retrieved from: <http://www.carestream.com/default.aspx?LangType=1033>

CereScan. (2016). Main page. Retrieved from: <https://cerescan.com>

Cerner. (2016). Solutions. Retrieved from: <http://www.cerner.com/solutions/>

Chen, L. (2015, June 4). 2015 Global 2000: The World's Largest Drug and Biotech Companies. Retrieved from: <http://www.forbes.com/sites/liyanchen/2015/06/04/2015-global-2000-the-worlds-largest-drug-and-biotech-companies/#68755de35768>

ClearCanvas. (2016). Home page. Retrieved from: <https://www.clearcanvas.ca/Home/ClearCanvasforResearch/tabid/486/Default.aspx>

CoActiv. (2016). Home page. Retrieved from: <http://coactiv.com>

Coins. (2016). Welcome page. Retrieved from: <https://portal.mrn.org/cas/login.php?rp=https%3A%2F%2Fportal.mrn.org%2Fportals%2Fprivate%2Findex.php>

CorTechs Labs. (2016). Home page. Retrieved from: <http://www.cortechslabs.com/neuroquant/>

CorticoMetrics. (2016). Home page. Retrieved from: <http://www.corticometrics.com>

Cyntegrity. (2016). Home page. Retrieved from: <https://cyntegrity.com>

Cyntegrity. (2016). Our Management. Retrieved from: <https://cyntegrity.com/about-us/cyntegrity-management/>

DeJarnette (2016). Our Management. Retrieved from: <http://www.dejarnette.com>

Dell. (2016). Unified Clinical Archive. Retrieved from: <http://www.dell.com/en-us/work/learn/healthcare-hospital-provider-uca>

Desitin. (2016). About Desitin. Retrieved from: <http://www.desitinpharma.com/about-desitin/about-desitin/>

Diluca, M. (2014, June 18) The Cost of Brain Diseases: A Burden or A Challenge?. Retrieved from: [http://www.cell.com/neuron/fulltext/S0896-6273\(14\)00488-7](http://www.cell.com/neuron/fulltext/S0896-6273(14)00488-7)

Economist. (2014, November 29). The Price of Failure. Retrieved from: <http://www.economist.com/news/business/21635005-startling-new-cost-estimate-new-medicines-met-scepticism-price-failure>

EMC. (2016). Home Page. Retrieved from: <http://www.emc.com/en-us/index.htm>

EMA. (2008). Guideline on Clinical Evaluation of Diagnostic Agents. Retrieved from: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500003584.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003584.pdf)

FEI. (2016). Home Page. Retrieved from: <https://www.fei.com/home/>

Flywheel io. (2016). Main Page. Retrieved from: <https://flywheel.io>

Grainger, D. (2015, January 29). Why Too Many Clinical Trials Fail -- And A Simple Solution That Could Increase Returns On Pharma R&D. Retrieved from: <http://www.forbes.com/sites/davidgrainger/2015/01/29/why-too-many-clinical-trials-fail-and-a-simple-solution-that-could-increase-returns-on-pharma-rd/#45e6d6d45f67>

Greene, S. (2016, July 11). Brain Disorders and Diseases Cost U.S. Economy \$1.5 Trillion, Underscoring Scale of Opportunity for Greater Research and Innovative New Treatments to Improve Health and Drive Prosperity, ITIF Study Finds. Retrieved from: <https://itif.org/publications/2016/07/11/brain-disorders-and-diseases-cost-us-economy-15-trillion-underscoring-scale>

Helena. (2013, March 8). Top 10 Software as a Service (SaaS) Companies. Retrieved from: <http://zeendo.com/info/top-10-software-as-a-service-saas-companies/>

Icometrix. (2016). Main Page. Retrieved from: <https://icometrix.com/#!/en/>

Imagilys. (2016). Brain Imaging Techniques. Retrieved from: <http://www.imagilys.com/brain-imaging-neuroimaging-techniques/>

Intelrad. (2016). Main Page. Retrieved from: <http://www.intelerad.com/en/>

InviCRO. (2016). Main Page. Retrieved from: <https://www.invicro.com>

Jac, D. (2013, May 8). Business models in the pharmaceutical industry: The case of Novo Nordisk. Retrieved from: <https://biostrategyanalytics.com/2013/05/08/business-models-in-the-pharmaceutical-industry-the-case-of-novo-nordisk/>

James, J. (2010, July 21). Why drug development is time consuming and expensive (hint: it's hard). Retrieved from: [http://scopeblog.stanford.edu/2010/07/21/mochly\\_rosen\\_lecture/](http://scopeblog.stanford.edu/2010/07/21/mochly_rosen_lecture/)

Jnguyen. (2012, April 09) Research Basics. Retrieved from: [http://web.stanford.edu/group/hopes/cgi-bin/hopes\\_test/neuroimaging/](http://web.stanford.edu/group/hopes/cgi-bin/hopes_test/neuroimaging/)

Kepes, B. (2016). Understanding the Cloud Computing Stack: SaaS, PaaS, IaaS. Retrieved from: <https://support.rackspace.com/white-paper/understanding-the-cloud-computing-stack-saas-paas-iaas/>

Key, D. (2013). SaaS Revenue Models Win in the Long Run. Retrieved from: <http://cloudstrategies.biz/saas-revenue-models-win-in-the-long-run/>

Lexmark. (2016). Vendor Neutral Archive. Retrieved from: [http://www.lexmark.com/en\\_us/solutions/healthcare/enterprise-imaging/vendor-neutral-archive.html](http://www.lexmark.com/en_us/solutions/healthcare/enterprise-imaging/vendor-neutral-archive.html)

Loni. (2016). Main page. Retrieved from: <http://www.loni.usc.edu>

Mach7. (2016). Main page. Retrieved from: <http://www.mach7t.com>

McKesson. (2016). Main page. Retrieved from: <http://www.mckesson.com>

Medicor Imaging. (2016). Main page. Retrieved from: <https://www.medicorimaging.com>

Merge. (2016) Radiology. Retrieved from: <http://www.merge.com/Solutions/Radiology.aspx>

MIM. (2016). Radiology & Nuclear Medicine. Retrieved from: [http://www.mimsoftware.com/markets/nuclear\\_medicine](http://www.mimsoftware.com/markets/nuclear_medicine)

NetApp. (2016). Main page. Retrieved from: <http://www.netapp.com/us/index.aspx>

NeuroVault. (2016). Main page. Retrieved from: <http://neurovault.org>

Neurosynth. (2016). Main page. Retrieved from: <http://neurosynth.org>

NordicNeuroLab. (2016). Main page. Retrieved from: <http://www.nordicneurolab.com>

Novarad. (2016). Main page. Retrieved from: <https://www.novarad.net>

OECD Publishing. (2015) OECD Health at a Glance 2015. Retrieved from: [http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/health-at-a-glance-2015\\_health\\_glance-2015-en#.V\\_KRycYshss](http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/health-at-a-glance-2015_health_glance-2015-en#.V_KRycYshss)

Olea Medical. (2016). Main page. Retrieved from: <http://www.olea-medical.com>

OnBase. (2016). Main page. Retrieved from: <https://www.onbase.com/en/>

OpenfMRI. (2016). Main page. Retrived from: <https://openfmri.org>

Osirix. (2016). Main page. Retrived from: <http://www.osirix-viewer.com>

Osterwalder, A. (2013, May 6). A Better Way to Think About Your Business Model. Retrieved from: <https://hbr.org/2013/05/a-better-way-to-think-about-yo>

Parkinson's Disease Foundation (PDF). (2016). Diagnosis. Retrieved from: <http://www.pdf.org/en/diagnosis>

Patel, N. (2015, March 26). 11 Revenue Streams for SaaS Businesses <http://www.forbes.com/sites/neilpatel/2015/03/26/11-revenue-streams-for-saas-business/3/#16b9e251f711>

PDF. (2016). Statistics on Parkinson's. Retrieved from: [http://www.pdf.org/en/parkinson\\_statistics](http://www.pdf.org/en/parkinson_statistics)

Pharmacelera. (2016). Home page. Retrieved from: <http://www.pharmacelera.com>

Pharmacelera. (2016). Enric Gibert. Retrieved from: <http://www.pharmacelera.com/team-view/egibert/>

Philips. (2016). Philips and Hitachi Data Systems to deliver next-generation data management solution for healthcare organization-wide access to billions of medical images. Retrieved from: <http://www.philips.com/a-w/about/news/archive/standard/news/press/2016/20160218-Philips-and-Hitachi-Data-Systems-to-deliver-next-generation-data-management-solution.html>

Phillips, T. (2016, February 26) Biotech Business Models, the balance. Retrieved from: <http://biotech.about.com/od/strategy/tp/BusinessModels.htm>

Pietrangelo, A. (2015, March 24). Multiple Sclerosis by the numbers: Facts, Statistics, and You. Retrieved from: <http://www.healthline.com/health/multiple-sclerosis/facts-statistics-infographic>

Pixyl. (2016). Main page. Retrieved from: <http://pixylmedical.com>

Prescott, JW. (2013, February 26). Quantitative imaging biomarkers: the application of advanced image processing and analysis to clinical and preclinical decision making. <https://www.ncbi.nlm.nih.gov/pubmed/22415112>



PricewaterhouseCoopers. (2009). Pharma 2020: Challenging business models Which path will you take? Retrieved from: <https://www.pwc.com/gx/en/pharma-life-sciences/pdf/challenge.pdf>

Prism Clinical. (2016). Home page. Retrieved from: <http://www.prismclinical.com/index.html>

Quantib. (2016). Main page. Retrieved from: <http://www.quantib.com>

Quibim. (2016). Main page. Retrieved from: <http://quibim.com>

Sectra. (2016). Main page. Retrieved from: <http://www.sectra.com>

Shiel, W. (2016, August 8) Magnetic Resonance Imaging (MRI Scan). Retrieved from: [http://www.medicinenet.com/mri\\_scan/article.htm](http://www.medicinenet.com/mri_scan/article.htm)

Siemens. (2016). syngo.share. Retrieved from: <https://www.healthcare.siemens.com/medical-imaging-it/syngo-share/syngo-share/features-benefits>

Skripka-Serry, J. (2013, Fall). The great neuro-pipeline brain drain (and why Big Pharma hasn't given up on CNS disorders Retrieved from: [http://www.ddw-online.com/therapeutics/p216813-the-great-neuro-pipeline-brain-drain-\(and-why-big-pharma-hasn-t-given-up-on-cns-disorders\)-fall-13.html](http://www.ddw-online.com/therapeutics/p216813-the-great-neuro-pipeline-brain-drain-(and-why-big-pharma-hasn-t-given-up-on-cns-disorders)-fall-13.html)

SyntheticMR. (2016). Home page. Retrieved from: <http://www.syntheticmr.com>

Tanner, A. (2014, January 6). Company That Knows What Drugs Everyone Takes Going Public. Retrieved from: <http://www.forbes.com/sites/adamtanner/2014/01/06/company-that-knows-what-drugs-everyone-takes-going-public/#456c858b71f2>

Trifermed. (2016). The CBDO concept. Retrieved from: [http://www.trifermed.com/the\\_cbdo\\_concept/](http://www.trifermed.com/the_cbdo_concept/)

Trifermed. (2016). Clara Nascimento, PhD. Retrieved from: <http://www.trifermed.com/team-member/clara-nascimento-phd/>

VolBrain. (2016). Home page. Retrieved from: <http://volbrain.upv.es>

Waterton, C. (2008, April). What imaging biomarkers are and how they are used. Retrieved from:

[http://cds.ismrm.org/protected/09MProceedings/files/Wed%20C39a\\_01%20Waterton.p  
df](http://cds.ismrm.org/protected/09MProceedings/files/Wed%20C39a_01%20Waterton.pdf)

WHO. (2007, February 22). Neurological disorders affect millions globally. Retrieved from: <http://www.who.int/mediacentre/news/releases/2007/pr04/en/>

WHO. (2016, February). Epilepsy. Retrieved from: <http://www.who.int/mediacentre/factsheets/fs999/en/>

Winter, A. (2016). What is Disruptive Health Technology?. Retrieved from: <http://www.dhti.cmu.edu/dhti/definition.asp>

XNAT. (2016). Home page. Retrieved from: <https://www.xnat.org>