CLINIKICK

Business Plan

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Medtech Innovations II: Prototyping and New Venture Development

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EXECUTIVE SUMMARY

PROBLEM

The enormous cost of research subject recruitment is a burden on clinical research. Annually, approximately $1.89 billion of the $7 billion clinical research funds is spent on research subject recruitment.[1] Even with the amount currently spent on recruitment, over 27% of all clinical trials fail to enroll research subjects, 75% fail to reach the target number of subjects, and 90% of all clinical trials fail to enroll in the allotted time.[1] The statistics indicate that serious deficiencies exist within the current recruitment strategies. As the number of clinical trials continues to rise, there is a dire need to improve recruitment methods.

SOLUTION

Clinikick is a user-friendly recruitment platform that seeks to provide a centralized database of all clinical studies. In the IRB clinical study approval form that clinical investigators must file prior to conducting studies, the investigators will be presented with a new option to list their study on Clinikick. If the investigators choose to list their study on Clinikick, they will provide their advertisement materials along with the study approval applications. With the addition of this service, the trial and advertisement applications are combined within a single step. The clinical investigators will no longer have to take additional steps to find recruitment platforms or submit separate advertisement approval forms to the IRB. The process of study and advertisement approvals will also be more streamlined for the IRB, because it can approve the study and its advertisements in one step. Since IRB database contains all the clinical studies, Clinikick communicates with its database to ensure that our platform provides a complete list of all active clinical studies. Ultimately, Clinikick reduces the amount of work for all parties involved, while consolidating research information that has traditionally been scattered.

MARKET AND CUSTOMER

$1.89 billion is currently spent on research subject recruitment.[2] Research centers interested in implementing Clinikick will pay a monthly subscription for its services. The monthly subscription fee is proportional to the number of trials that are posted from the research center.

TECHNOLOGY

Clinikick will be available as a web and mobile application. Clinikick communicates with the IRB database to display the advertisements that the clinical investigators have submitted. Interested research subjects can search for trials based on locations and keywords. The interface of Clinikick is especially user-friendly, which is critical for ensuring that potential research subjects can successfully find matches.

MARKETING AND SALES STRATEGY

The software and service will be marketed on various media outlets, including Facebook, Twitter, and LinkedIn. Google and Yahoo advertisements will also be used. Clinikick intends to launch its beta product with UCLA IRB and leverage the relationship to market itself to other institutions.

COMPETITION

[1] English, Rebecca A., Yeonwoo Lebovitz, and Robert B. Giffin. Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary. Washington, D.C.: National Academies, 2010. Print.

[2] http://www.mwbconsulting.com/downloads/patient.pdf

Current research subject recruitment methods are inefficient and produce less than desirable results. Prior to advertising clinical studies, investigators must receive approval for their trials and advertisements from the Institutional Review Board (IRB). Once the advertisement materials are approved, the investigators use social media platforms, flyers, and websites that list clinical studies to recruit for research subjects. These methods are not effective, because social media platforms contain extraneous information that can overshadow clinical research ads, flyers reaches a limited number of audience, and the current websites that list clinical trials are difficult to navigate. In addition to their poor interfaces, these websites list esoteric descriptions of the active clinical trials that can be difficult to understand for a person without a medical background. Furthermore, the websites tend to feature only clinical trials and neglect observational studies, which limit the opportunities available to a potential research subject. The websites also require investigators to create profiles and manually submit their advertisements, which can be a tedious process. With each investigator subject to a personal advertisement preference, there is an incomplete distribution of research information over an array of different platforms and sites, ultimately making it impossible for a potential research participant to be aware of all possible clinical studies.

ORGANIZATION AND KEY LEADERS

Clinikick was founded as a collaboration among Dr. Kim-Lien Nguyen, UCLA students Anthony Nguyen, an electrical engineer, Brett Harwin, mechanical engineer, Sophie Zhao, biochemistry, Eric Dunipace, medical student, and Art Center College of Design student, Jon Hsiung.

FINANCIAL PROJECTIONS

Institutional utilization of Clinikick has significant financial implications. Clinikick will yield a drastic reduction in patient recruitment costs, allowing more funds to be allocated towards other aspects involved in completing Phase I, II, and III trials. The increased funds and research subject participation dedicated towards the trials will consequently result in a rise of successful clinical research studies. This escalation in success rates will more than likely lead to an increase in institutional funding. Thus, Clinikick is fiscally beneficial to research centers.

CURRENT STATUS

Clinikick began in March 2015 as a result of the Medtech Innovations (MTI) course at UCLA. We are currently in negotiations with the appropriate members of the UCLA IRB in order to integrate and test our platform.

BACKGROUND

NEED STATEMENT: AN EFFECTIVE WAY TO CONNECT PATIENTS TO CLINICAL TRIALS.

Clinical trials face many issues that limit their effectiveness in achieving their goals. Knowing about these issues allows us to better understand the need statement and ensure that our solution to the need tackles a wide view of the whole problem.

THE PROBLEMS CLINICAL TRIAL INVESTIGATORS FACE

HIGH COSTS

In the United States, 27% of all trials fail to enroll any subjects, and worldwide the number is still high at 19%. 75% of US investigators fail to enroll the target number of subjects, and "90 percent of all clinical trials worldwide fail to enroll patients within the target amount of time and must extend their enrollment period."[3]

SLOW TRIALS

Some of these trials may take a long time to finish. In cases such as that of the Ebola outbreak in Africa, time is of the essence. The average time required to recruit an individual for a clinical trial may be as high as 6 months per individual, and even worse, the average time to recruit enough individuals may be as high as 2 years, depending on the type of trial. Today, there is no shortage of individuals waiting and available to participate in trials of treatments for the Ebola virus, but before the outbreak the number of possible participants may have been far more limited.[4]

IDENTIFYING QUALITY PARTICIPANTS

There are many ways that trials today recruit patients. Many trials in hospitals can identify patients who have come into the hospital for an unrelated reason once they are already there. Some trials start from physicians who own their own practice, who then see patients on a recurring basis. Likewise, there are physicians who work in a consortium of other physicians, and they can cross refer patients that they have to trials that each other know about. The consortium may have a monthly meeting of physicians, or an internal email listing, so sending out one mass email may be enough to inform several dozen physicians at once about a trial, and there is a good likelihood that among them that they have someone who will meet the requirements of the trial. Lastly but not least, posting advertisements on sites such as craigslist where people can see the advertisement and respond by themselves is also a very common way to for participants to be identified.

THE PROS AND CONS SURROUNDING RESEARCH SUBJECTS

Patients have varied reasons for participating in clinical trials. There are those who are altruistically motivated – they want to help advance the field of medicine (1:3 willing to do so). They may participate due to recommendation from their doctor, especially as they are convinced that the presence of IRBs means that their wellbeing is as important as the scientific research being conducted. Others are in it for themselves. It might be the money – many trials pay individuals to participate. Others seek a therapeutic benefit from the procedure or free medication. Through participating the trial, these people gain access to leading specialists as well as access to education about their treatment. For patients who are very ill, participating in a trial gives

[3] R. B. Gul and P. A. Ali, "Clinical trials: the challenge of recruitment and retention of participants," Journal of Clinical Nursing, vol. 19, no. 1–2, pp. 227–233, Jan. 2010.

[4] "NIH begins early human clinical trial of VSV Ebola vaccine." [Online]. Available: http://www.nih.gov/news/health/oct2014/niaid-22.htm. [Accessed: 11-Mar-2015].

them reason to get up every day. They may have no other options available to them, they will die whether or not the test this drug, so they my as well do it in case it works.

There are a variety of reasons why people may not participate in clinical trials. One big issue is the lack of awareness. Only ¼ people are able to even describe what a clinical trial is. For people who are aware, there are many fears that they might experience. Some fears include: getting a placebo, being a guinea pig, complicated protocols, quality of life issues such as (autonomy, side effects, loss of functional capacity), information too technical, theme of mistrust of researchers among minority communities, patients believe that clinical investigator is more interested in the research than the patient's well being. While not a fear per se, some individuals also express a preference for alternative and holistic treatments. With all of these things in mind, people may find that perceived risks oftentimes outweigh perceived benefits. Even when they are willing to participate, there may be no appropriate clinical trials available to certain individuals, or they may be disqualification due to protocol. Or, perhaps there is an appropriate trial, but then the person has confusion about what is covered in insurance, or issues with their workplace, transportation to the location where they need to be for the trial, the time it takes to travel there, and how to take care of their children while they are out.

PROS AND CONS SURROUNDING DOCTORS AND NURSES INVOLVED IN CLINICAL STUDIES[5]

The role played by doctors and nurses in helping recruit for these trials is not be underestimated. It is documented that the relationship between CRA and clinical nurse can influence patient's decision to enroll in a trial, helping to overcome barriers to participation, just as doctors. For doctors, group practices, and those close to cancer centers better than individual practices, and those farther from cancer centers, in recruiting patients. For cancer patients, doctors will typically refer patients at advanced stage of disease. Generally, patients with higher education levels, as well as middle aged or very young patients are more likely to be referred than those with lower education levels or more elderly patients.

The impact of the contribution of doctors and nurses however may be limited by various factors as well. Concerns may include doctors believe that clinical trials are inferior to standard treatments, doctors who do not know about trials that are going on, doctors who are concerned about the risks the trials pose to patients. When the doctors do want to present the information, they may find that it is complicated to explain the trials to the patients least they be confused. It may take a long time to explain well – time the doctor may not have. Finally, one of the strongest issues may be that there are issues of legal liability to the doctor who refers the patient to the trials – what if the patients die and the family sues the doctor for making the recommendation? All of these problems lead to lessened support by doctors to provide patients to trials.

[5] "Clinical Trials Recruitment and Enrollment: Attitudes, Barriers, and Motivating Factors" [Online]. Available: http://cro.rbhs.rutgers.edu/documents/clinical_trials_recruitment_and_enrollment.pdf. [Accessed: 08-Mar-2015].
"What is HIPAA Compliance?" [Online]. Available: http://www.onlinetech.com/resources/references/what-is-hipaa-compliance. [Accessed: 11-Mar-2015].

CURRENT SOLUTIONS

A. MYTOMORROWS (BASED IN NETHERLANDS. FOUNDED IN 2012)

Mission: myTomorrows helps patients access drugs that are still undergoing clinical trials.[1] These patients often do not have enough time to wait for the drugs to pass FDA regulations. Prior to the company's existence, patients excluded from clinical trials have difficulty accessing treatments still in clinical trials.

Method: myTomorrows provides a platform that connects patients, doctors, and drug companies, and facilitate the process of obtaining drugs not yet on market.[1]

Advantages: Government clearance does not require the company to supply the experimental drug, so myTomorrows negotiate directly with drug developers for access to treatments, facilitate the paperwork process, and gather data on the use of the drug.[1]

B. EPATIENTFINDER (BASED IN TEXAS. FOUNDED IN 2013)

Mission: ePatientFinder uses analytics technology to connect patients with cutting-edge treatments that are still in clinical trials or were recently approved by the FDA.[2]

Method: The platform connects its pharmaceutical, medical device and Contract Research Organization (CRO) clients with a network of clinics, hospitals and Accountable Care Organizations (ACOs) for the purpose of identifying and enrolling patients in clinical trials. ePatientFinder can help physicians use their electronic health records to connect patients with clinical patients, which involves a sophisticated algorithms and an innovative three-tier filtering process to help physicians target potential participants.[2]

Advantages: The platform is free for physicians to use.[2] Physicians are also paid by ePatientFinder when they meet with a patient to talk about clinical trial.[2] The company claims that all of their stakeholders are able to benefit from the platform. Life science companies are able to recruit faster for their clinical trials, which reduce the time for the drug to be approved and opportunities for the companies to market their new treatments. The physicians are also able to provide the most advanced medical treatments for their patients, which help reduce the time the physicians need to sift through countless numbers of journals and news articles for treatments that match their patients' needs. Insurers also benefit, because patients find more effective treatment options quickly, which cuts cost.

C. MOLECULARMATCH

Mission: MolecularMatch uses a software program that extracts information from public sources, such as government databases like clinicaltrials.gov, to create an easy-to-use online database where patients, with certain cancer mutations and other health characteristics, can be paired with clinical trial that will most help them.[3]

Method: Provides an online software platform that allows doctors and physicians to search specific cancers and mutations. The search results provide drugs and clinical trials that are related to the input.[3]

Advantages: Product is currently in beta testing, but the company intends to use molecular alterations to find the best treatment. This process accelerates personalized medicine by helping physicians find treatments faster.[3]

Disadvantages: When a matching clinical trial is searched, the information is not user friendly for patients. The website may be able to function effectively if separate tabs are designated for patients and doctors. The platform does not seem to be integrated with electronic health records, so the process may be time consuming for busy physicians. The platform would work better if the physicians could be automatically alerted.[3]

D. CENTER WATCH

Mission: At CenterWatch, the mission is to be the leading source of clinical trials information for both clinical research professionals and patients. To support its mission, we offer several professional, educational and informative services and resources from news and analysis on the industry to trial listings seeking study volunteers.[4]

Methods: CenterWatch provides information specifically for patients on its website. For example, CenterWatch provides a Clinical Trial Listing Service, which is a clinical trial database that contains thousands of active trials. Information on drugs and new medical therapies are also available for patients. CenterWatch also provides patients with health and educational resources about clinical trials and other health information.[4]

Advantages: An enormous amount of information provided about clinical trials information, drug information, and other resources for patients.[4]

Disadvantages: The website is not proactive in recruiting patients. Web page is crowded. Text is dense and information difficult to find. To help patients understand the information, less text and more pictures can help.[4]

E. EMERGING MED

Mission: EmergingMed's mission is to accelerate the discovery of new and better treatments for people with serious and life threatening medical conditions.[5] Since 2000, the Company's focus has been the creation of patient-centric tools and services that quickly and accurately connect patients and health care providers to clinical trials testing new therapies in development. EmergingMed is committed to getting the right information to the right person at the right time—always ensuring that information is presented in context and readily actionable.

Methods: EmergingMed collaborates with patient advocacy groups, trial sponsors, research sites and provider networks to manage patient identification, recruitment and retention.[5] EmergingMed's genomic solutions also provide customized clinical trial match results based on the specific biomarkers and genomic alterations identified by molecular testing.

Advantages: EmergingMed created its clinical trial matching and referral system to quickly and accurately connect patients with appropriate clinical trial options. They have also added personalized education and one-on-one support with Clinical Trial Navigators to help families make sense of these options, understand the narrow timeframes for joining a clinical trial, and identify and fix barriers that might otherwise interfere with a family's ability to seriously consider enrolling in a clinical trial.

Disadvantages: The layout is not patient friendly: dense text and difficult to find relevant information.

E. TRIALX

Mission: TrialX's mission is to enable patients to find and learn about clinical trials that match their health conditions, connect them with trial investigators, and ultimately to speed up the process of treatment approvals.[6]

Methods: Patient can use a web messaging platform called Dory to connect patients and trial investigators.[6] The patient is able to message the clinical investigators directly.[6] Investigators can list their clinical trials for free on the platform.[6]

Advantages: TrialX is the only company that is integrated with Microsoft HealthVault, GoogleHealth, and Indivo, which are personal health record vendors. TrialX benefits pharmaceutical companies, CROs, and hospitals seeking patients to recruit.

Disadvantages: The layout is not patient friendly, because the patient may feel overwhelmed with the amount of information provided. Also, the web messaging platform is difficult to find, although the interaction keeps the user engaged.

F. CLINICALCONNECTION

Mission: ClinicalConnection provides patients with a clinical trial database and patient recruitment services for the pharmaceutical development and medical device sectors.[7]

Methods: As stated on its company website, ClinicalConnection provide the following services: customized clinical trial listings, online patient referrals, database recruitment, tools to enhance study visibility on the web, and development of trial-specific websites. Clients of ClinicalConnection include medical companies; contract research organizations (CROs), academic research institutions, hospitals, physician practices and independent clinical research sites. To post studies on this website, the study centers are charged a flat fee.

Advantages: One aspect that distinguishes ClinicalConnection is that the company offers development of trial specific websites that can increase the visibility of a trial.

Disadvantages: Medical questionnaire is inefficient for patients, due to checkboxes that extend the length beyond what is reasonable.

- If the platforms can provide user-friendly information, that may increase patient interests in clinical trials.
- The method of finding relevant clinical trial is also often cumbersome.
- The best platform would extract information from electronic health records and send the recommendations to both patients and physicians.
- The stakeholders involved include patients, physicians, investigators, insurers, and treatment developers.

References

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[2] "Welcome to EPatientFinder." Welcome to EPatientFinder. N.p., n.d. Web. 11 Mar. 2015. <http://www.epatientfinder.com/>.

[3] "Begin Your Search To Find The Latest Cancer Therapy." MolecularMatch. N.p., n.d. Web. 11 Mar. 2015. <https://www.molecularmatch.com/>.

[4] "Helping People Connect with Clinical Trials." Clinical Research and Drug Information. N.p., n.d. Web. 11 Mar. 2015. <http://www.centerwatch.com/>.

[5] "Helping Patients Find New Cancer Treatments through Clinical Trial Matching - EmergingMed." Helping Patients Find New Cancer Treatments through Clinical Trial Matching - EmergingMed. N.p., n.d. Web. 11 Mar. 2015. <http://www.emergingmed.com/>.

[6] "TrialX Blog on Raising Clinical Trials Awareness." TrialX. N.p., n.d. Web. 11 Mar. 2015. <http://www.trialx.com/>.

[7] "We Bring Clinical Trials to YOU!" Clinical Trials. N.p., n.d. Web. 11 Mar. 2015. <http://www.clinicalconnection.com/>.

OUR PRODUCT

CONCEPT DESCRIPTION (WEB APP)

· The platform connects cancer patients to clinical trials conducted at UCLA.

· Main Feature of the App

o Using the IRB as a resource, we intend to contact clinical investigators and ask if they want to submit descriptions of their clinical trials in layman's terms. The description (preferably in bullet point format) should give the participant a basic understanding of the clinical trial conducted.

o The participants would register and search for clinical trials using keywords.

§ The participants also have the option of connecting their EHR (electronic health records) or PHR (personal health records) to the platform, which would allow the platform to automatically alert the participant when a match occurs.

o The platform contains a built-in chat service for the patient to contact the clinical investigator directly if a match occurs.

o The platform also allows clinical investigators to contact participants whose EHR or PHR match their clinical trial requirements. The platform de-indentifies patient information and would only provide the matches as Patient 1, Patient 2, etc. If the patient accepts the clinical investigator's request, only then can the clinical investigator speak with the patient.

SECONDARY FEATURES

o The web platform also provides information about clinical trials in layman's terms. Our research has shown that ¼ of the population do not understand clinical trials. Thus, we aim to educate as well as connect participants to clinical trials.

o The web and app platform also provides a section where participants can anonymously ask questions, similar to other Q&A websites like Quora. People who answer these questions would be experts. We believe that this feature would assuage some of the fears that may surround clinical trials.

o Once the participants sign up and enroll in a clinical trial, the platform also provides a news feed similar to Facebook's. The clinical investigator can post updates regarding the status of the clinical trial to all of the patients enrolled in the clinical trial via our platform. We believe that this feature enhances patient engagement.

o The platform has a referral feature that allows participants to refer patients to clinical trials. For example, a primary care physician can sign up using our platform and upload their patients' EHR (after obtaining consent from the patients) to the web platform. The platform would automatically alert the primary care physicians when a match occurs and allow the physician to refer the patient to the trial.

How do people interested in searching for clinical trials use the platform? (See Figure)

1. Users can sign up on our website platform. Users are welcome to make a new account or not make an account at all.

2. Users have the option of linking their account to their PHRs or EHRs.

3. Users search for clinical trials using keywords or their EHR/PHR.

4. Search results indicate the clinical trials that match the user and a short description of the clinical trial in bullet point format.

5. Users can choose to message the clinical investigators of the trials that they have matched. They can choose to provide name, email, and phone number. The phone number of the clinical investigator is also provided in case the person would like to call.

6. After the users chooses to message the clinical investigator, the only information that the clinical investigator receives at this point in the process should be name, email, and phone number. Security and privacy checks are maintained at all times to ensure that the process is HIPAA compliant.

7. The user has the option of sharing his or her EHR/PHR with the clinical trial investigator.

How do clinical investigators use the platform? (See Figure)

1. Clinical investigators conducing cancer trials should receive an email from IRB that recommends our platform.

2. Clinical investigators make a new account on our website or app platform.

3. Clinical investigators submit the relevant information regarding their clinical trials. The relevant information should include the phase of the trial, a short description of the clinical trial in bullet point format, the criteria of the clinical trial, compensation for patients, phone number, email, and location.

4. Our platform will approve of their posting before the public views it in order to verify the information and ensure that the information provided is easily understandably to the general public. This process should not take longer than 48 hours and the clinical investigator will receive an email following successful confirmation of their submission.

5. Once the posting is live on our platform, the clinical investigator receives emails or phone calls from people interested in learning more about their clinical trials. The clinical investigator can proceed to make appointments with the people interested in their trials.

6. The clinical investigator also has the option of actively searching for patients that match their clinical trials. The platform would only provide the matches as Patient 1, Patient 2, etc. If the patient accepts the clinical investigator's request, only then can the clinical investigator speak with the patient.

7. The platform can also alert the clinical investigator when a patient has registered who matches their clinical trial criteria based on EHR/PHR.

MARKET ANALYSIS

Current Market

The current market in clinical trials is huge both in terms of numbers of trials and in terms of costs. For instance, there are over 185,000 clinical trials registered with the government and it is estimated that 7 billion is spent every year on clinical trials and that 1.89 billion is spent annually to recruit patients.[1,2] Moreover, about $300,000 is spent to recruit patients for a Phase III clinical trial, on average, while the total cost of running one phase III trial is $20 million.[3]

Market Growth

Given the numbers above, it Is surprising that the growth in the number of clinical trials has accelerated over time. In 2004, the compound annual growth rate (CAGR) in the number of trials was already 21%. Since 2004, the number of registered clinical trials grew at a rate of 31%.[1] At this current pace, there will be close to a million trials registered with the US government by the year 2020.

Similarly, costs have been expanding, albeit at a slower rate. Between 2004 and 2011, pharmaceutical spending on Phase I, II, and III clinical trials expanded at a CAGR of 4.5%.[4] Admittedly, pharmaceutical spending on Phase IV trials decreased at a CAGR of 3.9% over this same time period, but we anticipate that our primary market will be in the first three phases of clinical trials and especially in Phase III.

One potential concern in market growth is that funding of the National Institutes of health has been stagnant or decreased over the last decade. For example, since 2010 NIH funding has decreased by approximately $1 billion. This could be a potential concern given that a large portion of the basic science research that helps generate new and innovative solutions needing clinical trials relies on NIH funding.[5]

Finally, one of the major difficulties identified by consultants, contract research organizations, and biotech companies was patient recruitment. Addressing some of this burden among the growing number of clinical trials, which also have increasing costs, offers a potential area for our service to grow into.

Competition

The current competitive landscape is growing more crowded by the day. Currently, we have identified 6 other firms working in this space divided into three areas: connecting patients to treatments, patient education, and assisting doctors enroll their patients in clinical trials.

In terms of connecting patients to treatments, myTomorrow, Emerging Med, TrialX and MolecularMatch run services that allow patients to identify clinical trials or treatments that might cure their diseases. However, these services do not allow investigators to search for eligible patients and they are not specifically built for clinical trial recruitment.

In terms of patient education, Center Watch presents patients with an enormous amount of information regarding clinical trials, but they do not connect them directly to these trials. In terms of assisting doctors to enroll their patients, ePatientFinder allows doctors to connect patients to clinical trials using their electronic health records. However, it is not a service focusing helping consumers find trials that might be right for them.

Figure 1. Average Cost by Clinical Trial Phase.

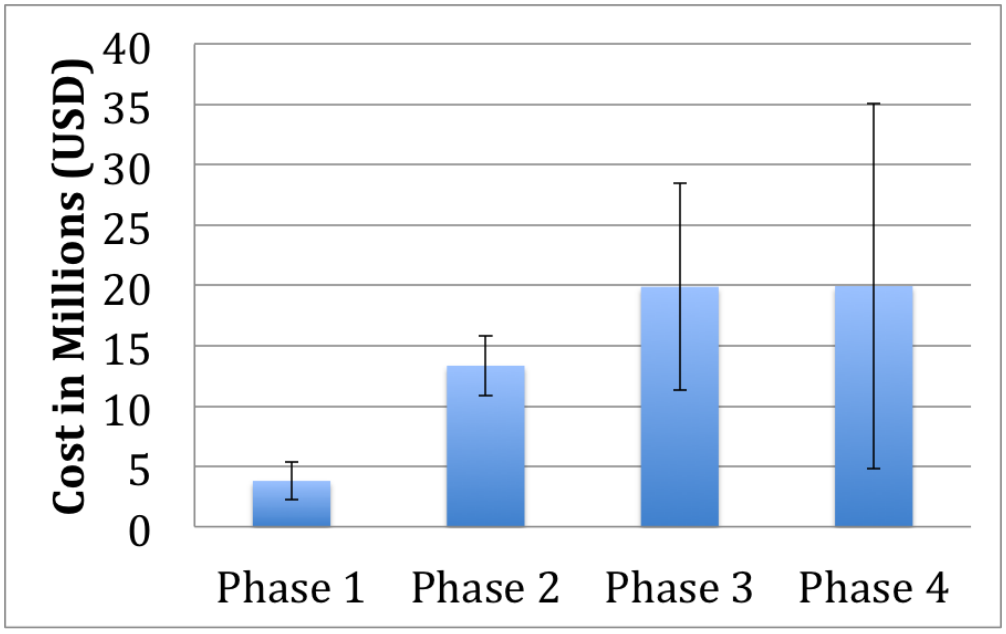


Figure 2. Number of Registered Clinical Trials from 2000 to 2015. 2015 numbers are up to current date only.

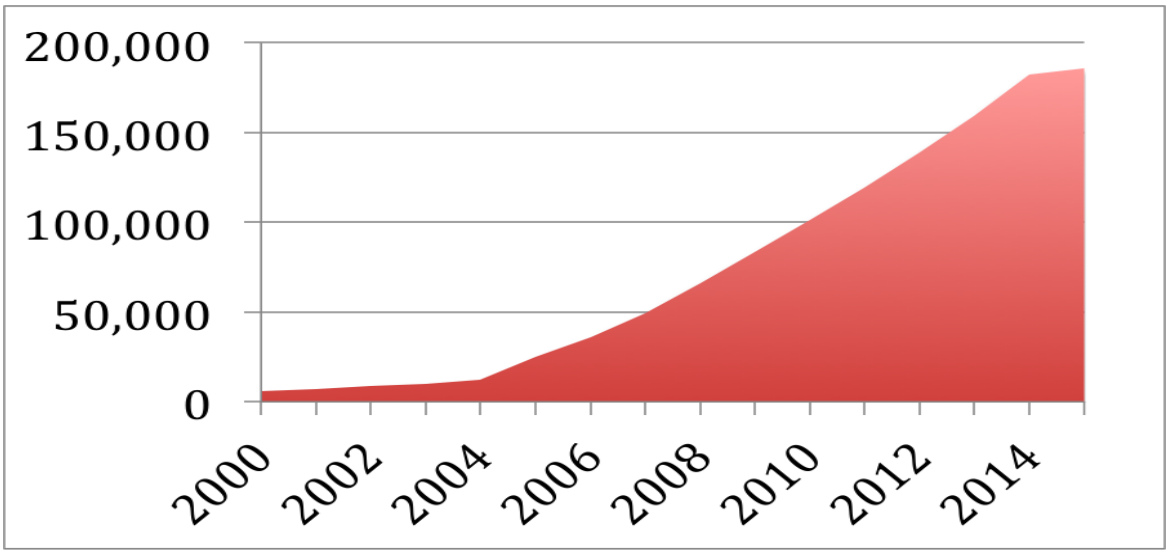
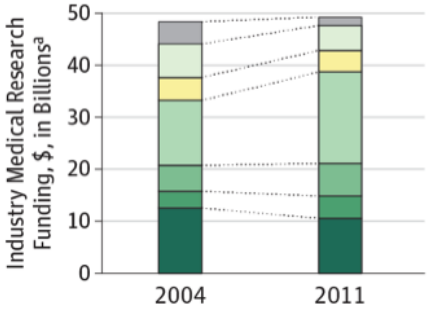


Figure 3. Drug company research spending by clinical trial phase. Reproduced from Figure 4 of Moses et al (2015).



Phase of Research	Industry Medical Research Funding, $, (%), in Billions[a] 2004	2011	Compound Annual Growth Rate, %[b] 2004-2011
Uncategorized[c]	4.2 (9)	1.7 (3)	-11.9
Phase 4	6.4 (13)	4.8 (10)	-3.9
Approval	4.5 (9)	4.1 (8)	-1.2
Phase 3	12.6 (26)	17.6 (36)	4.9
Phase 2	4.9 (10)	6.2 (13)	3.3
Phase 1	3.2 (7)	4.3 (9)	4.1
Prehuman/preclinical	12.5 (26)	10.6 (22)	-2.3
Overall	48.3	49.3	0.3

[1] US National Institutes of Health. Trends, Charts, and Maps. 2015. https://www.clinicaltrials.gov/ct2/resources/trends. Accessed March 8, 2015.

[2] Bowden M, Mackenzie-Lawrie S. Accelerating patient recruitment. Pharmafocus. 2001.

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OPERATING PLAN

MILESTONES

Our goal is to have Clinikick active at all UCLA affiliated institutions by the end of 2016. We have a series of milestones that we aim to achieve by that time that will ensure our success

Quarter	Goals	Budget
Q3 '15	Develop Alpha Test In-House Formation of LLC	50K
Q4 '15	Testing Recruitment with Dr. Lien's Clinical Trials Refine Interface	100K
Q1 '16	Expanded testing with more clinical trials, Such as all the trials in the cancer department	
Q2 '16	Release to UCLA Ronald Regan Hospital Examine data on completed trials	200K
Q3 '16	Release to UCLA affiliated hospitals	300K
Q4 '16 And beyond	Expand to institutions unrelated to UCLA	1M

SALES AND MARKETING

To find patients to participate in trials listed in Clinikick, we will have an extensive recruitment process to reach large amounts of people in the UCLA area. We can use more targeted styles of recruitment as well as less targeted styles.

TARGETED RECRUITING.

DOCTORS AND NURSES

Especially with the advent of the new Obamacare laws, everybody should have health insurance, and thus, a doctor they go to normally. By reaching out to all doctors in the UCLA area, Clinikick would thus be able to reach all other people who might be able to participate in studies by proxy.

OTHER CAREGIVERS

Clinikick is a web based platform for matching patients for all sorts of clinical trials, which typically do not target young, healthy individuals. More likely is that the trials will be applicable to elderly, sickly patients, who may not be able to easily use the internet and find out information about their diseases, especially in more rehabilitating cases. Instead, they may only be able to find out about clinical trials through their caregivers, who might be at a nursing home, hired help, close family members, or even friends.

PATIENT GROUPS

Patient groups are groups that support patients of a particular disease, through awareness, screening, prevision, and meeting in person. Targeting these groups of people for recruitment will allow us to very easily match clinical trials that involve a certain type of disease with patients who are suffering from those diseases. These groups may be able to help by allowing us to attend meetings, sending out emails about us on our behalf, or even introducing new members to us when they sign up.

UNTARGETED RECRUITING

SOCIAL MEDIA

OTHER MEDIA

We can of course use traditional print ads in newspapers and grocery store magazines, television ads during popular viewing times such as the Super bowl, or billboards on heavily congested parts of the freeway. These methods are not specifically targeted, however they would be affective at reaching out to many lay people.

REFERAL PROGRAM

To reap the most benefit from untargeted recruiting, we can have a referral program in place. People might encounter our untargeted recruiting and think that Clinikick is not related to them directly, but they might know somebody for whom Clinikick might be right for them. To build a good community relationship and encourage potential customers, we can give cash rewards for successful referrals.

FINANCIAL ANALYSIS

As we mentioned before, the average cost per patient recruitment is $1,200. We would like for our platform to reduce this amount by half or more. We think that using Clinikick, an investigator will be able to find potential patients within minutes of creating their trial instead of days, weeks, or months, and because of this they will be able to find significant reductions in costs.

We are looking at a monthly subscription model to charge institutions that utilize Clinikick. The fees charged to an institution per month would correspond to the number and type of trials that they list with us. We can give a better rate to those institutions who chose to contract with us on a yearly or multi-yearly basis.

To attract new institutions, we might allow a trial period where an institution provides to us a half-dozen trials or so, and we will guarantees that we will be able to provide X number of patients for each of those trials or their money back. Once they are satisfied with our performance, we can then start billing them at the normal rate.

In addition to the monthly subscription cost, we may also charge per patient recruited costs for certain types of trials. For instance, if an institution has a trial for a type of disease that we have not partnered with any patient groups for that disease, that is an additional cost that we would need to endure for that trial. We might then chose to charge additional fees based on the cost of reaching out to those patient groups, per patient. Recall that $1200 was the average cost of recruitment. However, for some trials the cost of recruitment per patient will be significantly higher, and they may still want to find those patients very, very badly. We could charge them a nominally higher amount, and then they would still be very happy. We would benefit as well, because by that point, they would have covered the cost we have to outreach to those new patient groups, and this will make it easier for us to successfully match those patients for similar trials in the future.

RISK ANALYSIS

The risks that we may encounter can be considered in terms of technical risks, market risks, and financial risks.

TECHINCAL RISKS

Technical risks involve the creation of our web platform. For our initial platform, we need to be able to communicate with the IRB at UCLA in order have the information about the clinical trials transmitted into our system to be stored until the trial is ready to be posted. We have already faced difficulties communicating with UCLA and have thus far been unable to begin integrating with their technology. Without having technical cooperation from the system used to vet clinical research information, our platform will have no trials listed.

Great effort will be made to ensure that the web platform we create is modular and built for wide compatibility, because we understand that as we connect to different institutions in different cities and states, there will be different technologies that we need to work together with in order to have all these different types of trials in one system. This risks can be mitigated early on by contacting many different IRBs and doing research into what kind of technology they use to manage their data before we begin forming our system. Some of them have custom software that we need to interface with, while others use commercial available solutions, and so we can communicate directly with those vendors to be compatible with many IRBs at once.

Our website will also need to be able to handle large amounts of data at one time. As we add more and more institutions to our system, they will then come into Clinikick with massive amounts of clinical trials, and they will want us to be able to list all of their trials right away.

MARKET RISKS

The risks in the market would come in two forms – not enough clinical trials being listed in our system, and/or not enough patients enrolling in the clinical trials that we do have listed.

NOT ENOUGH TRIALS

Compared to our competitors, we feel that the risk that we will not have enough trials is low, because we will be partnering with IRBs directly, and that will provide us with large amounts of trials that are centralized to geographic location.

NOT ENOUGH PATIENTS

This is a major issue that is faced by all of our competitors as well. As previously mentioned, 20%, or 1 in 5, Americans will need to be enrolled in a clinical trial if we are to meet the anticipated demand for patients for new trials over the next 10 years. Ideally, we would want all Americans, or even all people on Earth, to have awareness of clinical trials, but this is not a realistic goal. In order for our platform to be successful, however, we will need to reach a majority (over 50%) of people near the IRBs that we partner with. Since we will first partner with UCLA, we would want to reach all individuals within say, 15 miles of UCLA and be inform them about clinical trials and CliniKick. Extensive marketing and outreach will be the only way to mitigate the risk that Clinikick may initially lack patients.

FINANCIAL RISKS

The financial risks of Clinikick are variable. After it has been created, we do not need to spend that much money in order to support an existing web framework. The costs of data storage and computing power in the cloud scale with usage, so as we add new IRB's into our system, the fees that we will charge them will absolutely cover the additional cost associated with supporting them.

Apart from the technical costs, the main costs of Clinikick will be marketing and outreach related costs. Especially if we chose to use traditional advertising methods such as print ads, TV ads, and billboard ads, a lot of money will

need to go into advertising for us to reach a large audience. We also need to have educated and passionate staff that can represent us when we need to talk to new doctors, nurses, patient groups, and other caregivers because these staff have the most important job of getting these very targeted forms of recruitment to buy into our platform and believe in our cause. It would not be sufficient to have a car salesman sell our platform to these highly educated groups; they must be met with technical competency and an understanding of their problems.

REGULATORY STRATEGY

Clinikick's regulatory strategy is to partner with institutional review boards (IRBs) and health systems to stay HIPAA compliant. When we do utilize health records, we must obtain approval from the individual patients whose medical records we want to allow investigators to search. At a health system like UCLA, this will not involve much additional effort since such provisions already exist to inform patients that students may be present during their health care encounters and that their treatment may be use for educational purposes. However, at other health systems, this may be more of an onerous task.

As such, we propose a regional expansion strategy that will first encompass the University of California system before moving to other health systems. We will utilize the connectivity built into the University of California IRBs to expand our services to the teaching hospitals extant in the UC system like UCSF, UC San Diego, UC Riverside, UC Davis, and UC Irvine. Do to the massive and bureaucratic nature of these health systems, we anticipate that such expansion will take 5-10 years so we do not have any concrete plans beyond this point. However, another organization we plan to target is Kaiser.

INTELLECTUAL PROPERTY

Unfortunately, the idea does not currently have room for proprietary intellectual property, and there are several other firms with competitive patents. One patent was granted in 2011 for an HTML based web-portal that uses a patient survey to connect patients to appropriate clinical trials.[1] Another was granted in 2010 that describes the batching of patients into groups with similar characteristics so that they are easily rankable for use by clinical investigators.[2] Given these extant patents, Clinikick will need to think diligently about patentable property.

[1] Knight SC, inventor; Quintiles Inc., assignee. Recruiting a patient into a clinical trial. US patent 7,904,313. March 8, 2011.

[2] Dahlke DV, Capelli C; Texas Healthcare & Bioscience Institute, assignee. Clinical Trial Navigation Facilitator. US20100332258 A1. Dec 30, 2010.

TEAM

Eric Dunipace – Eric recently completed his first year of medical school and has considerable research expience. Eric's knowledge of the medical field and institutional experience provides important insight. Eric has helped develop strategic methods to approach the current problem while appeasing the end users.

Sophie Zhao – Sophie is a biochem undergrad at UCLA. Sophie has extensive research experience and has been able to provide similar insight. Her organization skills and punctuality have been paramount throughout the development of this idea.

Anthony Nguyen – Anthony is currently working on obtaining his Master's degree in electrical engineering. Anthony is a brilliant coder and talented engineer. He will serve as the primary developer and head of IT.

Jon Hsiung – Jon is currently in the process of obtaining his graphical design degree. Jon has an aptitude for aesthetics and a deep understanding of interface design. Jon will serve as the primary graphic designer for Clinikick.

Brett Harwin – Brett is a mechanical engineer with a considerable medical background. A jack of all trades, Brett thrives at presenting complex concepts in easily digestible ways. He has served as the pitch man and the primary team member to interact and Network with potential investors.

CONCLUSION

Clinical research is a 7 billion dollar industry. About 2 of those 7 billion dollars are spent solely on patient recruitment. Even with those gaudy numbers, 75% of all clinical studies fail to enroll their target number of patients and a quarter of all clinical studies fail to enroll even one participant. These shockingly inefficient recruitment rates speak to the shortcomings of the current recruitment methods that are being employed. Clinical investigators rely on sites such as craigslist and social media platforms like Facebook and Twitter. While passing out flyers seems to be a rather outdated method of advertisement, it is still one of the primary methods used by clinical investigators. Several sites do exist with the sole intent of advertising potential clinical studies, however, complicated UI's and an overall lack of research information makes them useless.

Clinikick is platform that seeks to facilitate patient recruitment by collaborating with IRB database. With a focus on a user-friendly interface, Clinikick will consolidate all research info into a centralized hub. Using encrypted code and a simple pass thru action, Clinikick will reduce the work necessary for clinical investigators to market their research study. Furthermore, a user-friendly hub with all available information guarantees that the potential clinical participant will be able to find whatever they are looking for. Ultimately, this platform has considerable financial implications for the institution that chooses to employ it. First and foremost, Clinikikc will directly save the institution money as it will reduce the amount of money allocated toward patient recruitment. This will lead to more successful research, and more research funding, illuminating the ripple effects of Clinikick. Ultimately, this platform will vastly increase the efficiency of patient recruitment, which will save money for any institution while benefiting mankind as whole.