While services like Amazon and Uber are efficient in their respective industries, they are vastly different from the process of recruiting a patient to a clinical study. For a similar use case that is employing technology effectively, we can examine job search websites. Sites such as Indeed, Monster, and Dice allow job seekers to search and apply for jobs and also allow for companies to contact employees based upon a profile the job seeker has filled out and uploaded to the website. After a job applicant has applied for one job or has voluntarily created a profile on the website, applying for additional jobs is drastically simplified. So much so, that it’s possibly to apply directly on a mobile device as resumes and contact information are saved to the user’s profile. In only 2 clicks, a user can apply to a job.

In addition, employers can contact the employee themselves when a job matches. As companies have their own HR firms, given these tools, they no longer have to wait for applicants to submit an application for a job, but can leverage their own resources to review profiles of job seekers to find a match and reach out to potential employees directly. This system allows the employer to be proactive in finding its own candidates.

A similar model can be applied to clinical trials. The website will allow patients to search for clinical studies as usual; when an applicant locates one they are interested in, they will click apply and enter into a standard application page. From here they will be able to provide basic to advanced information regarding their condition, as well as upload any supporting documentation as necessary. After applying to one study, they will be given the option to have their profile searchable for study facilitators to contact the patient regarding similar studies. At the same time, when applying for another study, the user’s information will be called from their profile, and the user will be able to submit an application in a few clicks without submitting any additional personal information.

In terms of implementation difficulty, cost and effort, all should be relatively low. This is existing technology and is less a revolutionary step than a necessary at this point in time. As opposed to the job search website example, there is a legitimate concern about patient confidentiality. There will have to be steps taken to secure data and also withhold names and identifying information from study facilitators when they search through user profiles to find matches. Even still, these are not significant hurdles and should be accomplishable without significant effort.

Ideally the solution would be a government hosted website as these two examples are: <http://clinicalstudies.info.nih.gov/>, <https://clinicaltrials.gov/ct2/home>. This would promote a greater sense of trust for users, as their personal information is submitted to a government ran website versus a third party website.

Costs for creation of this type of website and implementation may vary. If an enterprise CRM system like SAP is in the backend, it may cost hundreds of millions to implement. If the platform is simpler and an existing web platform is adopted, costs should be far cheaper. To reduce costs, I would recommend a proof of concept be built with a relatively small team first, before involving a larger team. This can prevent costs from ballooning quickly. The base functionality should not be hard to implement, rather the challenges will be ensuring user security and clearing any regulatory hurdles regarding maintaining patient information.

As the website is streamlined and optimized, marketing the website should be a top priority and factored into the cost analysis. In addition to traditional advertising campaigns (print and media), information needs to be put directly into the hands of the patients in the hospitals in the form of pamphlets promoting the website. I’m not too aware of how information is regularly provided to patients, but perhaps an incentive program for hospitals could help facilitate the distribution of information if that is an issue. Potentially some sort of grant directly to the hospital or medical practitioners for distributing the information if that is feasible. Wide scale advertising via transit ads (subway, bus) may be a good idea as well for the completed website. From this cost estimate, advertising on NYC subways would have a wide reach and acceptable cost staring at $1500 for a four week run of 30 interior subway ads. (<http://www.bluelinemedia.com/subway-advertising>).

In addition, on the website itself, there should be much more information regarding clinical trials in general and the benefits of trails. Looking at the current clinicaltrails.gov website, the “Learn about clinical studies page” is not written in a manner to convince a patient to participate (<https://clinicaltrials.gov/ct2/about-studies/learn>). Benefits are not discussed and there is nothing done to effectively market clinical trial participation to the patient. The website overall is a bit drab and is not engaging; the site is devoid of any pictures at all and is not personable.

With greater exposure, along with a website that facilitates higher intake, participation rates should increase.

Actual Cost, Time, and Resourcing of Solution Estimate

As an estimation of actual costs, I located a website design company that will design small, medium, and large sized websites. Estimated top end costs for a large website is around $30,000 USD (<http://www.executionists.com/blog/much-website-cost-2015/>). From webpagefx.com, a full featured website with an enterprise level of background integration ranges from $43,500-$97,750 (<http://www.webpagefx.com/How-much-should-web-site-cost.html>). These cost estimates are relatively small compared to soaring costs associated with an SAP Enterprise CRM system. For reference, I was part of the project team that implemented an SAP CRM system for the US Department of Agriculture for their MIDAS. The project staffed more than 200 persons and had costs estimated at $305 million (<http://www.gao.gov/assets/330/321447.pdf>).

In terms of resourcing for implementation for a Proof of Concept (POC), ideally a web design company can be engaged for a full featured website with full functionality (1 Project Manager, 2 backend developers, 2 front end developers). For the POC, I would minimize the emphasis on security details in the initial build, as long as the information is not live. This may represent a major cost in later phases in terms of both development and any regulatory hurdles. Current clinicaltrial.gov staff representatives would be engaged in requirement gathering phase and specification design and signoff. 3-6 business analyst resources familiar with hands on functionality would be involved day to day. Managers(1-2) and directors(1-2) of the current site will be looped in as well for formal sign-off and weekly status updates with the project manager. For this POC, I would engage studies to build around. Ideally these studies would have a long term patient intake period and be of a fair size for testing purposes, so that as testing and development is near completion, we will hopefully be able to accept patients into the system. During development and initial test phases, mock patients will be created for testing purposes until security is improved. At a later phase we will be able to use live patient data within a closed system for a phased go-live. Go live may initially or the study facilitators only to manage intake manually while interacting with the website. The next phase after that would be patients registering in these studies independently through an invited website link, so that only pre-screen participants can enter via the website. For development and complete testing itself, I estimate a period of 6 months for the POC(1.5 months requirements gathering, 2 months development, 1.5 months testing cycles) and 6 additional months for completion of a holistic go-live ready system (2 months additional development, 3 months testing, 1 month knowledge transfer to staff). When the project is complete, the website will be maintained by the existing clinicaltrails.gov staff; they will receive knowledge transfer training from the any temporary project staff. Note that the development conducted in the POC should be directly applicable to the full featured site. This estimate is not inclusive of any regulatory hurdles of maintaining and patient information or audits to ensure patient information is secure.

Appendix:

Current System and Proposed System Flow diagram

