DESCRIPTION

About 80% of cancer clinical trials (CCTs) complete successfully—8% terminate because of insufficient patient accrual[1]. While CCTs are diverse and each new one is unique, the fact that 4 out of 5 cancer clinical trials complete successfully presents a tremendous opportunity to learn from the past. The proposed solution comes in three stages, all with the overall goal of helping principal investigators (PIs) learn to run sufficiently accruing clinical trials from this unorganized and untapped reservoir of knowledge.

- Stage I: establishing a real a value proposition
- Stage II: a minimum viable product
- Stage III: software as a service product
  - A graphical, web-based software that allows PIs to see which already completed CCTs are most similar to his/her planned or in progress CCT, and to learn from them.

HOW IT WORKS, WHAT IT LOOKS LIKE

The way each of the three product stages works is described below. All stages of course will require lots of iteration and interaction with principal investigators to develop a high value product, and exact product manifestations are subject to change.

- Stage I: **establishing a real value proposition** entails talking to PIs about how they currently learn about recruiting best practices for CCTs, what they are, and if they would be interested in learning from previously successful PIs who have run similar CCTs (e.g. same disease, same study type, similar study design, etc.). Talking directly to potential customers and listening to them allows the product development team to design something that provides real value.

- Stage II: if results from Stage I are positive, **a minimum viable product (MVP)** will then be developed to provide value to PIs at a low cost. A proposed MVP is a "manu-matic" matching service for PIs to find and talk to other PIs who have run similar, completed clinical trials about recruiting best practices. This may require some parsing and organization of the clinicaltrial.gov data and manual searching and matching to find similar completed clinical trials to a given PI's clinical trial.

- Stage III: the Stage II product will evolve into a **software as a service (SaaS) product**: a graphical, web-based software that allows PIs to see which already completed CCTs are most similar to his/her planned or in progress CCT, and to learn from them.
  - An idea for the graphical representation of clinical trial similarity in such a product is a network graph view, where different trials are displayed as nodes, with the current user's/PI's trial in the center (and colored differently). The links between each node represent the similarity of the two clinical trials that are connected, with stronger similarity—or higher "similarity score"—links being darker in color/shade.
  - Once the current user clicks on a node, a side panel appears where the user can see details about the clinical trial, how exactly it is similar to the clinical trial he/she is running, who that CCT's investigator is, and any appended information such as a video from the investigator explaining best practices for recruitment, protocol design, etc. that he/she used.

Standard technologies for rapid web development will be used, for example Amazon Web Services and a flexible and powerful web application framework like Flask (Python seems to be the language of choice here as the data analysis, statistical, and machine learning communities are very strong).

COST AND TIME TO DEVELOP

The estimated costs and time to develop the solution will depend on the stage:

[1] 20% of cancer clinical trials are not completed, 40% of those fail because of low accrual, http://www.medscape.com/viewarticle/819930

Product Stage	Cost	Time
Stage I	minimal cost	3 months, working part-time
Stage II	$2,000, primarily graphic design	6 months, working part-time
Stage III	$250,000, salary for 2 full time engineers and 1 full time clinical trial expert + overhead	6 months, working full-time

At Stage I, the cost is just the time spent to establish a value proposition, estimated to be a couple months of time. At Stage II, some algorithms may need to be written, and a good designer will need to be hired to design the website. The product in Stage III will require the full-time dedication of a small team to execute well on both the product vision and business model (at this point it is essentially a seed stage startup company).

VIABILITY AND SUSTAINABILITY

The viability of a product is driven by the value it creates. The solution described here provides direct value to principal investigators and their funding sources: it helps them reduce the amount of money, time, and scientific research lost to clinical trials that terminate due to low patient accrual. It does so in an "individualized" way, where a principal investigator who uses it for his/her own clinical trial gets back uniquely relevant insights, instead of generalized recommendations. The solution is also low cost, web-based, and easy to use, undercutting CROs who do provide "recruitment consulting services" and filling the void where PIs do not have that kind of support.

The sustainability of a product is driven by the barriers to entries it creates. Aside from the benefits of a small, fast, and flexible startup providing a low-cost, high-quality product, digital information based solutions maintain sustainability in a positive reinforcement loop: as the product helps PIs run clinical trials with sufficient accrual, those PIs contribute more information about their successful trials to the product's database, which makes the product even more valuable and allows it to help even more PIs run successful trials.

Another important point is that through the constant refinement of our product alongside the PIs we work with, we will be at the forefront of other obstacles that make designing and running clinical trials inefficient, and thus have the opportunity to develop other software and platforms in solving those problems.

IMPACT

Stakeholders will include the principal investigators, who will be the primary users of the above describe product/service, the research institutions and biotechnology companies that fund the clinical trial, physicians and patients because their clinical trial experience could change, and other 3rd parties involved in the clinical trial process (e.g. CROs).

Though difficult to quantify the number of patients that such a product could impact, decreasing the percentage of cancer clinical trials that terminate early because of insufficient accrual can dramatically bolster the pace of scientific progress and the many lives that impacts. Doing so in a focused, low-cost way—here, leveraging existing data and information to close the accrual gap—makes such impact even more scalable.