

## **Proposed Solution**

Describe your solution: Science 37 offers end-to-end clinical trial services in a completely novel operating model. We bring research to patients, through our patient-centric networked clinical trial approach. A Networked Clinical Trial (NCT) is one in which investigators, coordinators, and administrators are geographically dispersed or decentralized. Using this model, we are able to recruit patients from anywhere. All participants-- investigators, staff, and patients-- are connected by the Science 37 end-to-end trial system and supported by our mobile telemedicine trial platform. From beginning to end of participation, all aspects of research will be focused around the patient's home and local system of care. Instead of traveling long distances to participate in a cancer trial, patients will participate from right where they live. We utilize social media, digital marketing, and existing patient and doctor networks to recruit for cancer clinical trials and provide large-scale, disease-specific outreach to patients. Once patients learn about a trial, they can enroll, consent, and begin participating from home, using a mobile device with Science 37 proprietary software. Principal investigators remotely monitor and connect with patients through secure HIPAA-compliant telemedicine technology while engaging with local healthcare providers, labs, and infusion centers. The mission of Science 37 is to accelerate biomedical discovery by creating a new model that shifts the center for research from traditional institutional sites to the patient's home and local healthcare system. Applying this innovative approach to cancer research will increase participation and improve the patient experience, leading to faster and better trials.

How will you do it: The Science 37 patient-centric approach uses best practices in digital recruitment strategies to reach patients online. We will create new, diagnosis-specific website pages, and deploy social and search-based advertising to reach patients. We will partner with nonprofit organizations, patient advocacy groups, and individuals who are sharing their disease stories online to spread the word about our trials. We will partner with existing online patient and physician networks, and create new ones. With online communities, patients feel more involved and supported, and can be notified quickly and efficiently about open clinical trials. Since our trial enrollment is independent of patient location, our online referrals can reach broader audiences that include patients, their friends, family, and local physicians who can all be empowered to participate in the research process.

How does it work: Science 37 will partner with investigators and sponsors to design and manage patient-centric clinical trials for cancer. These trials will recruit online, enroll and monitor patients from their homes, utilize local labs, primary care providers and oncologists, and communicate with patients through telemedicine. NORA (Network Oriented Research Assistant) is the Science 37 proprietary mobile data collection tool that allows patients to interact directly with the study team and manages all trial-related data from multiple investigators or sites.

What does it look like: Using the Science 37 approach, cancer patients will be able to take part in clinical trials no matter where they are located. Family and friends can help patients find Science 37 trials online and refer them. Patients will also find information about trials on social media, websites, and search ads. They will be able to sign up immediately and securely, interact with the Science 37 investigators, and begin participation in trials. Real-time access to study staff will increase retention in trials and enhance trust in the research process. NORA ensures patient engagement and adherence throughout the trial.

How will you implement it: NORA is already a functional digital platform that has been used successfully in both prototyping and interventional phase III trials. Science 37 currently has all of

the tools to implement patient-centric NCTs to cancer patients. The next step will be to implement and test the model in a cancer trial.

Where will you implement: Science 37 will work in collaboration with our own oncologist-investigators, other consulting physician-investigators, centers of excellence, and/or sponsors to use NORA to recruit patients into trials. Using the Science 37 approach, we can cover the entire United States population depending on the medical licensure of the investigators.

Who will be involved (stakeholders): Science 37 will partner with key patient advocates, community advisors, cancer research institutes and investigators, and study sponsors to bring patient-centric NCTs to cancer research.

How much will it cost to create the solution (an estimation): Science 37 has successfully built and implemented NORA and our entire new operating model by leveraging telemedicine and regulatory expertise. Only incremental costs to develop cancer-specific digital recruitment tools and build new adaptations and extensions to NORA for cancer clinical trials are required. The cost of the trials themselves are the limiting factors.

How much will it cost to implement the solution (an estimation): The cost of an industry-sponsored phase III trial for a cancer medication can easily exceed \$10 million. The average cost of a trial run by NCI is \$1 million per trial. We believe that by utilizing Science 37, the cost of each trial can be reduced by 30-50%. Because recruitment is major barrier in the success of a trial, we recommend implementing a pilot trial to prove that the Science 37 model can enroll patients faster, and maintain them at a higher percentage of participation in a trial.

How many people will be impacted: Patient-centric NCT implementation will directly impact and benefit the patients participating in a cancer clinical trial; the exact number will depend on the scale of the trial and how many patients are to be recruited. By increasing participation in cancer clinical trials, we will help patients and physicians determine which medications are safe and effective in a much faster fashion. The results will impact cancer patients, their families, and the healthcare system as a whole.

How long will it take to create the proposed solution: We anticipate that it will take about 2-3 months to create active online community groups based on different forms of cancer and to advertise to respective cancer experts about the existence of these groups. NORA has already been created and is currently a functional platform in use in a 7-state phase III registrational clinical trial for a rare autoimmune disease. We recommend testing the improvements in recruitment/retention by having Science 37 engage in trial planning with sponsors who are developing novel anti-cancer agents or with innovative groups willing to work towards new approaches to anti-cancer drug discovery using genomics and precision medicine. We believe we will significantly speed enrollment of patients and increase retention compared to traditional research sites, demonstrating our ability to improve the patient experience.

Why will it work? Why is it viable: Science 37 empowers patients to take an active role in trial participation no matter where they live. The Science 37 platform approach overcomes the major barriers of geography, awareness, and trust – giving patients with cancer access to the best oncology researchers and cutting edge research from the comfort of home. Science 37 has already implemented this decentralized model in rare autoimmune disease research in seven states with a major pharmaceutical sponsor. Applying this approach to cancer trials is an exciting next step that we believe is very likely to work and be sustainable moving forward.