# What is your proposed solution to addressing the barriers?

#### Describe your solution

Using intuitive search fields, CTcue instantly matches patients and trials based on EHR patient data. Our solution neither requires a complex query design nor a need to involve data experts; clinicians can now find eligible patients using standard medical terminology in just a few mouse clicks.

Our matching algorithm will continue to search as patient data gets updated and can alert the hospital medical team in advance and during a consult, thus increasing trial inclusion awareness. The team can invite patients. Physicians won't miss a patient-trial match, while saving tremendous time and effort. On the other hand, should patients request to participate in trials, an overview will be available instantly.

#### How will you do it?

We enable physicians to search through patient records on keyword searches and improve the queries with intelligent algorithms. We focus on helping physicians by giving them the tools to answer medical industry's burning questions like trial feasibilities and timelines.

#### How does it work?

A web application in the cloud where pharmaceuticals and physicians alike can create queries to search for very specific patients. The web application will send the query to the local search engine at the hospitals to generate a list of eligible patients, which can only be accessed by an authorized physician inside the hospital. The physician can validate and, if necessary, make the necessary changes to the list. The number of eligible patients (the count, not the patient data) can be returned to the person submitting the query and the physician can contact the patients to ask if they would like to participate in the trial.

#### What does it look like?

An incredibly simple and intuitive web application. Through extensive user testing we have created a clean and user-friendly interface where users can insert trial criteria in standard medical terminology.

#### How will you implement it?

The users can insert trials and criteria and share these with colleagues and partnering sites through a secure web application in the cloud (Software as a Service). Healthcare institutes will receive a local installation of the intelligent search engine to maintain patient data privacy and security.

# Where will you implement it?

An application in the cloud (SaaS) and a search engine at the healthcare institutes.

## Who will be involved (stakeholders)?

Hospitals and other healthcare institutes, and life science industries (Pharmaceuticals and Contract Research Organisations-aka Sponsors).

Since healthcare institutes have access to Electronic Health Records, their adoption is crucial. To facilitate and accelerate adoption, healthcare institutes will have free access to the CTcue platform. Sponsors of clinical trials, having a financial interest in trials and studies will pay a license fee.

Part of the success of the matching platform is due to early involvement of all stakeholders. Monthly testing sessions with representatives of all parties involved will ensure that together we build a solution we all want and need.

#### How much will it cost to create the solution (an estimation)?

The first full release will cost \$ 200.000- to develop. However, the platform will generate value before the full release because of our agile development methodology.

# How much will it cost to implement the solution (an estimation)?

There are no costs involved to implement the solution. Life Science Industries will use the online SaaS platform, thus needing no implementation. Healthcare Institutes provide access to EHR's they receive their local implementation for free. They do need to provide a local server and connect an existing EHR backup to the matching engine. These initial cost will range from nihil to a maximum of \$ 5.000 of hospitals internal costs.

# How many people will be impacted?

Only 15% of trials are completed on time, with over 50% of delays being attributed to patient recruitment. Trials are often stopped due to a lack of patient recruitment, as often (up to 50%) investigator sites fail to recruit a single patient. We believe the physician is the most important patient recruiter. CTcue improves the process where it has real impact, i.e. facilitating patient recruitment. Since the current patient recruitment process is rather unclear and unstructured, we strongly believe that our novel solution will make a big difference.

Chunhua Weng et al. 2011 showed 2,5-fold improvement in recruitment rate over the conventional methods by using real-time screening alerts. Given that real-time screening is an additive feature of a much wider platform, going by our conservative estimates we aim to achieve a 4-fold increase in patient recruitment rates.

CTcue will hugely impact the outcome of clinical trials and studies. In addition to better utilization of scarce resources (i.e. clinicians hours) at hospitals, we firmly believe that CTcue will accelerate the drug discovery process. On full integration our disruptive innovation will tremendously shorten phases I – IV of clinical trials, thus potentially saving millions of lives.

# How long will it take to create the proposed solution?

Building such a solution in accordance with QA parameters would require 2 years of product development. However, we have been working with agile development methods, thereby generating value and assessing its effectiveness from the first day of development.

# Why will it work? Why is it viable?

Efficient recruitment of patients in clinical trials remains one of the biggest challenges for pharmaceutical companies. According to the IBM Institute for Business Value, patient recruitment consumes 27% of the cost of drug development – that is US\$15 billion annually worldwide. Currently 34.366 trials are recruiting patients worldwide, while in 2013, 1.798 trials recruited patients in the Netherlands. CTcue will be free for use for academic studies and trials, while industry sponsored trials and studies will be charged pay-per-use licence fee, understandably a huge saving.