

Clinical trial recruitment in the information age

Tom Dorsett speaks to Stella Bennett, Commissioning Editor

Tom is a founder of ePatientFinder. Before ePatientFinder, he was a partner at Chandler Morgan Consulting where he assisted numerous health IT organizations with their business development and revenue models. Before Chandler Morgan, he served as president of iMedicor, a publicly traded health information exchange company. Prior to iMedicor, he was president and CEO of NuScribe, provider of the market's first health information exchange coupled with a professional networking platform.

Q Tell us a little about your professional background. What began your interest in clinical trial recruitment?

Sure. My background is largely in health information technology. I have been in the space for about 16 years and I founded a company in 2003, that provided a lightweight electronic health record (EHR) and took the company through an acquisition in 2006. Afterward, I worked for the acquiring company for a few years. I wanted to create a new venture again, and I did not want to go back into the EHR space specifically, because it is highly competitive and most of the dominant players had already been established. Rather, I wanted to be able to do something with the foundation that was being created, especially here in the USA, around the American Reinvestment and Recovery Act [2], which was funding the mass adoption of EHR and further, do something with the data that would be highly beneficial to patients. In 2008, my youngest daughter Elizabeth was born with a large birthmark that covers about 40% of her left leg. We took her to a specialist to try and figure out what was available in terms of a treatment. He explained that the standard of care, the pulsed dye laser, was largely ineffective on extremities. And so, I asked what was going on in clinical trials, knowing that is where future opportunities were accessible

today, and he mentioned one trial but also that I should go on to Clinicaltrials.gov [3], and take a look around and see what was out there. Upon doing that, I found over 20 trials, and thought to myself, "well, that is really an interesting disconnect, I wonder if that is an actual problem." After really digging in, I came to realize that it is a massive problem. A total of 86% of all clinical trials run behind because of recruiting oriented delays. I then set about pulling together a team that had both clinical researcher backgrounds, as well as those with a health IT background and pulled together what ended up being a very unique model for identifying patients for trials.

Q Could you describe the ePatientFinder platform?

The platform connects our life science clients, which are pharmaceutical companies, device manufacturers and contract research organizations (CROs) with a network of clinics, hospitals and accountable care organizations for the purposes of identifying patients for Phase II and Phase III trials. We publish information about the trial on the platform, including high-level information to educate referring physicians, the geographic site locations and the inclusion and exclusion criteria, and it is curated and directed to the



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appropriate referring physicians in the right geographies and specialties. The physician is always in the driver's seat, so they are able to opt in to the trial if they feel like it is going to be beneficial to their patients. Our data science team also takes the inclusion/exclusion criteria and translates that into an EHR-optimized query, so that when that physician opts in, it initiates our three-tier process. The first tier is the data query, which is run on the EHR data – our platform is integrated directly to the referring physician's EHR. The query will identify a shortlist of patients who are qualified at a high level. However, the reality is that, even though EHR data are getting more robust, it is still not nearly robust enough to satisfy the highly subjective areas in these protocols, which are all very different, like fingerprints. Nevertheless, we have two more subsequent filtering layers to address those subjective areas, including an interactive voice response survey that is integrated into the platform to take patients through a series of questions that address areas that are never going to show up in the EHR data. If they pass, we actually schedule them to come in for a consultation with their own physician. If they pass that consultation – if the physician feels that they are a good fit – they are referred over to the closest trial site. That, essentially, completes the circuit. We are working with the patient to make certain that they are prepped and have understood some of the basics of clinical trials. We are not performing informed consent, still happens at the site, but we make sure the patient gets there, shows up and is comfortable with the process.

Q So, what would you say are the key benefits of such a system to physicians & patients?

To physicians, there are several key benefits. They are actually compensated for conducting the consultations, which is great, especially in the USA, where physicians are getting paid less and less, as Medicare and Medicaid reimbursements are continuously getting reduced. What is more important, we find in really communicating with our referring physician network, is that, it creates great opportunities for the patients. And it is not for every would-be referring physician, there is a specific type of physician that wants to be associated with this. Certainly, physicians who really care about their patients, and want to see them get the best possible treatments, which in many cases of course lie in the clinical research domain. What we also find is that when those patients show up for that consultation that they are extremely grateful, and happy that for the first time, that their physician has gone out and proactively sought a new type of treatment for their chronic disease, and has reached out to them. The patients have typically never experienced that from any physician they

have worked with, and so it creates a new level of patient satisfaction for physicians, which is very important, and helps retain those patients as well. Obviously for the patients, they are getting access to treatments that they would otherwise be completely unaware of. It is a very small percentage of the population that proactively goes out and seeks clinical trials for themselves.

So, what is different about us (ePatientFinder), really, if you look at some of the other recruitment services out there...they are really relying on catching the attention of that very small portion of the population that is seeking clinical trials for themselves, whereas, we are proactively working directly with physicians to help take trials to their patients, which has never really happened before effectively. You look at some scenarios where you might have a principal investigator who has a private practice, and who has great relationships in the community and typically their trial might be running behind. So they might try and reach out to some of their friends who are also physicians in the community and say, "can you help me by referring me a few patients? I am in danger of potentially losing this trial." That physician might say, "sure, I would be happy to," but the huge problem is not only do they have to keep top-of-mind awareness, and remember to begin with that their friend is running a trial as they are going through their very busy day seeing patients, but further they have got to apply those complex inclusion/exclusion criteria to their own patient base to try and figure out who is going to be a fit. The reality is that it just does not really happen very frequently at all.

And so, what our process does is really automate that whole continuum, and makes it plausible for physicians in the community to actually refer patients to sites.

Q What do you think the future holds for clinical trial design & recruitment?

I think what is really lacked in the past is good data. For the first time in the USA, there is a proliferation of good clinical data. European countries are starting to catch up, especially the UK, which is a market we are planning to enter shortly, and then some of the other western European countries, where we are hoping EHR adoption will pick up. We have other means of working around the EHR, but those data are critical to really starting to evolve trial design and recruitment. What we are actually able to do in addition to the recruitment piece is help refine protocols, based on the data that we have access to and help identify the bottlenecks. We have already done this for clients: identify bottlenecks in the protocol that are creating friction, and allow them (trial designers) to remove those, so that the recruitment in and of itself is a lot easier.

With recruitment, we have done something very unique in our model, by leveraging EHR data and what is more, actually leveraging referring physicians. We feel like that really is where the future is at. There will always be a need to capture those patients that are out proactively looking on the Internet, but we feel that by and large, it is going to be data driven.

Q What are your thoughts on wearable devices, social media & phone apps? Are they useful tools for patient outreach & monitoring?

I think for monitoring, absolutely. Especially wearable devices. You might have seen that our partner Medidata has been doing some really interesting things in that area; they actually conducted a clinical trial recently. Medidata has also partnered with Garmin™ [4] to start utilizing wearables in clinical trials. These are great for data capture. I think social media can be important for identifying patients, because there are certain sites out there that are disease-state specific, that create opportunities for patients to communicate with one another and to provide some of their data. That can be useful, and then of course phone apps are ubiquitous at this point that they are great for self-reporting, especially for some of the new 'virtual trial' models have started to emerge over the past couple of years. I think they can be very powerful for communicating directly with patients throughout the trial process, and in some cases avoiding to have patients come in for so many site visits, so we will start to see more and more of that as time goes on.

Q Are you currently involved in any new projects?

I am a little limited in terms of what I can discuss, but I can say that as a company, we are starting to move upstream and offer services for protocol refinement as well as site selection. As our network grows, we are able to do that more and more effectively.

Q What do you think has been the biggest advance in the field of clinical trial design in the past decade?

I think access to clinical data. Right now, we partner directly with some of the largest EHR companies; most of those companies are making their clinical de-identified datasets available to life science companies. Fortunately, this is not competitive in any way to what we do. I think that really helping some of the pharmaceutical companies that acquire these datasets to do some interesting things. Our process is a little different, in that we work with de-identified data, but we also work with identifiable data. We are not only able to refine protocols and identify sites, but we are actually able to identify patients in those bases, whereas, when you work only with de-identified data you cannot really accomplish

this very important function. I think leveraging clinical EHR data in general is going to drive a lot of advances, and I think we are really just starting to scratch the surface.

Q In a recent interview, you described your platform as a 'disruptive' way of addressing the challenge of patient recruitment. Could you please elaborate on this for our readers?

Certainly. When we say 'disruptive', we are doing something that is never really been done before successfully. There have been a number of attempts at leveraging clinical EHR data over the past decade to identify patients and create a working model for recruitment, but all of those actually ended up failing because those organizations were focusing solely on the data itself. Going back to one of my earlier statements, the data itself just really are not robust enough to make it work. We had to come up with a platform that has multiple tiers of filtering. Most of every other company right now, and we partner with some of these companies, focuses on marketing directly to the patient or aggregate consumer data. These companies can actually plug into our platform and access the network. We are the first company to successfully incorporate a network of referring hospitals and clinics. The results we are achieving are fantastic and we are bringing costs down as well.

Q Are there any changes you would like to see in the next few years across the field of clinical research?

I know this is a little more specific to the USA, but there is a new bill that has been proposed by Congress that really aims to streamline clinical research, and there is some interesting potential. Otherwise, I believe that taking the process to a more virtual state could be hugely beneficial. One of the challenges that we see with patients is that we can find patients all day that fits the criteria, but there is a lot of difficulty in just getting them out to the sites. They may be elderly, they may have disabilities and their transportation to sites can be very complex. In many cases, patients simply do not want to take the time to drive across town multiple times to participate. Once they find out that they have to make ten or 20 visits over the course of a year or so, the whole process just becomes very unappealing to them. I think if we can really start to progress to a more virtual, it would make a massive difference.

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