ceocfointerviews.com

Issue: June 11, 2018

CEOCFO Magazine

With a model of conducting selected study visits at patients' homes, GlobalCare Clinical Trials, LLC is enhancing patient enrollment into trials and decreasing dropout rates resulting in getting life-enhancing drug to market faster

Gail Adinamis
Founder & Chief Executive Officer

GlobalCare Clinical Trials, LLC
www.globalcarect.com

Contact:
Robin Marcus
480-473-4585
rmarcus@globalcarect.com

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

"GlobalCare brings patient centricity to clinical trials."
- Gail Adinamis

CEOCFO: ***Ms. Adinamis, what was the vision when you founded GlobalCare Clinical Trials and where are you today?***
Ms. Adinamis: The vision was to create a more patient-centric approach to clinical trials. Historically the biopharmaceutical industry was very good at creating sophisticated protocols however they did not take into account the practicality of patients to participate in these trials. It was very difficult for patients to come to the investigator sites for frequent visits and stay long for various tests and assessments. My vision was to make study participation more convenient and comfortable for patients by conducting selected protocol visits at the patient's home or alternate location. By doing so, this would increase patient enrollment, decrease dropout rates and ultimately decrease the development timeline and help speed the delivery of life-enhancing products to the market.

CEOCFO: ***It sounds like an excellent idea; why wasn't it done a long time ago?***
Ms. Adinamis: When I developed this model over 25 years ago, everyone asked why we had not done this before, and there was no good reason. I think there just wasn't the pressure on the industry to change. However, it now takes about ten to fifteen years to develop a new molecular entity and over $2 billion. Protocols are becoming more complicated and more procedures are being required so the traditional model is not sustainable. There is pressure now from regulatory agencies (e.g., FDA) and patients to reduce development time and costs.

CEOCFO: ***Is this the standard today?***
Ms. Adinamis: It is not an industry wide standard yet but it has gained tremendous traction over the last few years. It is still an innovative service model but recognized in the industry especially in the areas of oncology, neurology and rare diseases. It is being implemented in trials

by many biopharmaceutical companies proactively rather than as a rescue service for studies that are behind in enrollment or retention.

CEOCFO: ***What have you learned about the interaction with patients over the years?***
Ms. Adinamis: I think this is best illustrated by the testimonials that we receive from patients. It allows them to maintain their normal daily lives, whatever that is, and provides for a better quality of life. They are already compromised by their disease, so if we can minimize any changes or challenges to their normal daily lives, they truly appreciate it. They would much rather be at home with their family getting a blood draw, than traveling to the investigator site and perhaps spending half a day to get their blood drawn.

CEOCFO: ***What are the challenges in doing this at home and what do the people going into the homes need to understand?***
Ms. Adinamis: Our network consists of coordinators within specific countries. Currently we are in over 60 countries. Our country coordinators are generally private practice physicians, who oversee and manage skilled nurses within their country to conduct the home visits. These nurses are selected based not only on their proximity to the patients, but on their experience with the specific patient population (e.g., disease state) being treated as well as the services that are being requested. For example, if we are supporting a pediatric oncology study, our nurses are going to have to have pediatric oncology experience. They will be familiar with the patient population and how to communicate with them and their families.

CEOCFO: ***Are there particular types of trials of focus for GlobalCare?***
Ms. Adinamis: The majority of our studies are currently in oncology, rare diseases and neurology. In particular rare diseases is very important. A rare disease affects less than 200,000 Americans. These patients live distant to the centers of excellence where these studies are being conducted. Historically that has made it virtually impossible for most patients to participate in studies because they would have to travel across state lines or country lines to participate. Pharmaceutical companies were not investing in drugs for rare diseases because it would take too long and cost too much to enroll a sufficient number of patients. They would need to fly these patients to these centers for all their study tests and assessments. Now we are able to take the study visits to where these patients reside so many more patients now are able to participate in studies and the studies are in fact enrolling quickly within or ahead of target timeline.

CEOCFO: ***How do you vet clinicians across the world?***
Ms. Adinamis: We first conduct a comprehensive country analysis. We profile the healthcare system and delivery of care, assess current clinical trial trends and regulations, and profile the nursing profession – how are nurses trained and what are they qualified to do. We then complete a comprehensive screening process for our country coordinators and nurses to make sure that they not only have the right education and skill sets but that they fit our company culture. We generally conduct face-to-face qualifications and this entire process has proven to be very successful.

CEOCFO: ***What is involved in keeping the blood samples secure, safe, and the proper temperature or other requirements?***
Ms. Adinamis: The two most common services that we provide is drug administration and blood draws. Both of those have special processing and handling procedures as well as transportation requirements with temperature controls. We set up study-specific logistics to manage this. For example, drugs may be transported in validated temperature controlled shippers with temperature trackers that ensure that they stay within the proper temperature ranges. We do the same thing for blood samples. We provide nurses with everything they need in order to draw and process those samples in the patients' homes. We provide them with portable centrifuges, and if these samples need to be aliquoted and frozen, we provide them with dry ice and shipment to the central lab following the temperature requirements where they will be analyzed.

CEOCFO: ***What are the regulatory challenges?***
Ms. Adinamis: That is one of our biggest challenges. You can imagine regulations change regularly for every country. Recently the General Data Protection Regulation (GDPR), came into effect 5/25/18, so we had to make sure we complied with regulations to protect personal data from individuals residing within the EU. We stay informed to any regulatory changes so that we can ensure proactive compliance in each of the countries we operate.

CEOCFO: ***How is business?***
Ms. Adinamis: Business is terrific. We have been doubling virtually every year. I was just recognized for being in the top fifty fastest-growing women-owned companies in the country. I think that there is a true need for the service and a desire for the service within the clinical trial industry.

CEOCFO: ***How are you reaching out to prospective clients and how do you standout at a conference?***
Ms. Adinamis: The quality of our services and reputation has been our strongest marketing tool. We have been very fortunate to have numerous repeat clients. We receive referrals from our clients to other sponsors as well as referrals from investigator sites and central labs. When speaking at conferences our service model is recognized as an innovative, patient-centric and cost efficient model, so individuals are eager to reach out to GlobalCare.

CEOCFO: ***Where does cost come into play?***
Ms. Adinamis: There are different ways to look at cost. One is that we feel that by providing these services, we can significantly increase the enrollment rate into studies and decrease the dropout rates. Typically there are 15% to 40% of patients that will drop out of the study. We can decrease that to less than 5%. As a result, the overall development timelines are shorter. If you shorten your development timeline by months or years, what does that cost mean for the sponsor? We know that a blockbuster drug has anticipated revenues of over $2 million a day, so not being on the market for several months to a year can be significant. Another way to look at cost is the actual cost of conducting a study visit. If you look at a patient with a rare disease, where the sponsor is actually flying the patient from their home to the investigator site, the cost is drastically greater than having a local nurse visit the patient in the comfort and convenience of the patient's home.

CEOCFO: ***Do your potential customers understand where that cost analysis comes in or are they sometimes surprised when you explain?***
Ms. Adinamis: I think they understand and appreciate the cost benefits of using these services. In clinical trials time is money, a race to the market. There is always tremendous pressure on a pharmaceutical company to enroll quickly and complete their studies as soon as possible. These are services that they are investing in, and realize a large ROI.

CEOCFO: ***How does the personal touch help with the dropout rate?***
Ms. Adinamis: By having a nurse go to the patient's home and spend one-on-one time with the patient, they get to know these patients and their families, pets, and hobbies. They develop a bond and that is important in motivating patients to remain in the study. I think that is one of the biggest factors that results in the very low dropout rate.

CEOCFO: ***Are there services you offer that are not getting the traction you expect?***
Ms. Adinamis: Not at this time. I think that we have had very good reception to the utilization of our services in the home or the patient's workplace or for children that may be at summer camps or families that are going on vacation.

CEOCFO: ***What do you focus on, day-to-day as CEO?***
Ms. Adinamis: I focus on quality and customer service. I think that our growth is limited to how fast we can scale while maintaining our same level of quality. I also focus on ensuring that we provide the best possible service for the patients.

CEOCFO: ***What do you do to focus on the quality?***
Mr. Adinamis: We conduct a lot of internal training. We go over best practices with our internal staff and we also bring all of our country coordinators together annually to go over best practices and how we can always move towards performance improvement.

CEOCFO: ***What surprised you as GlobalCare Clinical Trials has grown and prospered?***
Ms. Adinamis: I guess I surprised myself that we have been able to expand our services so quickly. The company was incorporated in 2010, so in eight years we have gone from services in no countries to sixty countries. Also, having such a good utilization by some of the largest pharmaceutical biopharmaceutical companies in the world has been pleasantly surprising.

CEOCFO: ***What is next for GlobalCare?***
Ms. Adinamis: Now that we have reached a particular size, our next focus will be implementing technologies into our processes to streamline our activities such as e-document software so that we can easily upload and download study documents.

CEOCFO: ***Why is the company important?***
Ms. Adinamis: GlobalCare brings patient centricity to clinical trials. Ultimately, we are developing these products for patients so we need to keep them first and foremost in mind.