The Leading Global Provider of Ambulant Health Care Services for Clinical Trials, GlobalCare Clinical Trials, Ltd Conducts Selected Study Visits at Convenient Locations for the Patient for Biopharmaceutical and Medical Device Companies

Healthcare Clinical Trials

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Gail Adinamis
CEO

BIO: Gail Adinamis provides vision, leadership, strategic planning and oversight for GlobalCare Clinical Trials, Ltd. Ms. Adinamis is an accomplished executive with over 30 years of comprehensive phase I-IV clinical trials experience, including over 12 years of global clinical trials management at Abbott Laboratories and Astellas Pharma US. Ms. Adinamis founded the business model for centrally managed in-home and alternate site services for clinical trials in 1992. Ms. Adinamis is an industry thought leader and has spoken at over 25 industry conferences. She is an entrepreneur with strong business development and operational expertise along with a proven track record for success. She established and headed clinical trials divisions for three national home infusion companies. She was also the founder, President and CEO for a niche clinical trials service organization providing a mobile network of clinicians to speed patient recruitment and increase compliance and retention for sponsored clinical trials. Ms Adinamis was recognized for two consecutive years by INC 500/5000 as being among the leaders of the top 5000 fastest growing private companies in the United States.

About GlobalCare Clinical Trials, LTD:
GlobalCare Clinical Trials, Ltd is the leading global provider of ambulant health care services for clinical trials. GlobalCare provides innovative, GCP-compliant services for biopharmaceutical and medical device companies by conducting selected study visits at locations convenient and comfortable for the patient (e.g., their home, workplace) when travel to the investigator site is not practical. GlobalCare’s network of high skilled nurses and physicians provide blood draws, pharyngeal swabs, ECGs, study drug administration, clinical assessments, questionnaires, training and data collection. GlobalCare’s traveling clinicians provide patients with a convenient way to participate in trials regardless of study duration, frequency of visits, their disease state or distance to the study site. Additionally, GlobalCare’s patient-centric approach helps to accelerate patient recruitment and improve study patient compliance and retention.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Ms. Adinamis, would you tell us the focus of GlobalCare Clinical Trials? 
Ms. Adinamis: GlobalCare’s main focus is to conduct selected clinical study visits at locations that are convenient for patients. The traditional clinical trial model requires patients to travel to the investigator sites for their protocol related tests and assessments. We know this can be very challenging and inconvenient for patients and 90% of the delays in clinical trials are due to patient recruitment. Some of the main reasons for difficulties in recruiting patients are that the investigator sites do not have convenient hours, they are far from where the patient lives or patients lack transportation. GlobalCare takes a very patient centric approach and takes the studies to the patients in the convenience and comfort of their home, workplace or other alternate settings such as a travel location.

CEOCFO: What are some of the challenges inherent in working outside the traditional method? 
Ms. Adinamis: Mostly it is educating sponsors and investigators on this new model and how to implement it. Once they understand the model the common reaction is, “Why have we not done this before?” Once people understand how the model works it gains traction quickly. Typically our services contracted through the sponsor and it is complimentary to the sites and the patients.
CEOCFO: Why has this not been done before?

Ms. Adinamis: I founded the model in 1992 when I was recruited by a national home infusion company to set up a clinical trials division. That is when I first started coordinating and conducting home visits specifically for study patients. So this service model has actually been in existence for over twenty years and it has been used by small companies to the top ten pharma companies in the world. It is still considered a new and innovative service model and is certainly not mainstream yet. However, it is used commonly by some companies and I anticipate that it will continue to grow in popularity over the years.

CEOCFO: What are some of the difficulties in not having the control of one setting and going out into the field and how do you make sure everything is as it should be?

Ms. Adinamis: At GlobalCare we develop very comprehensive ambulant care training manuals that are specific for each study. We employ extensive standardization in our procedures and have a QA department focused on ensuring compliance. We have a network of Country Coordinators in each country who are trained to educate our local service providers in their local language. We currently provide services in over twenty-five countries and it is important that the nurses fully understand their responsibilities for the trial.

CEOCFO: How do you know when you are working with a service provider that is across the globe that they are really capable of providing the level of service that you want?

Ms. Adinamis: We have comprehensive screening and qualification processes coupled with in-country oversight. For example, in the US we only use licensed and accredited homecare agencies and conduct background checks to ensure that we have properly educated and qualified resources that we then further evaluate and train on study specific requirements. We collect and maintain quality metrics that help us to ensure that things are being conducted according to protocol and study procedures.

CEOCFO: How are you able to use technology to facilitate your program as well as ensuring the confidentiality and the credibility?

Ms. Adinamis: The protection of patient information is very important on a global basis. Every country has its own data protection and patient privacy regulations. Utilizing technology is challenging in this arena. Any technology that we employ is usually provided by the sponsor since each sponsor has its own platform in technology that they want to utilize or not utilize. Any technology must comply with local and national regulations.

CEOCFO: Are you involved in recruiting patients?

Ms. Adinamis: We are not involved directly in recruiting patients. That task is still the responsibility of the sponsor, the CRO and the sites. However, by offering our services to potential study patients, more patients are willing and able to participate. The sites are also able to recruit patients from a much broader geographic area. Our services actively come into place once patients have been enrolled into the trial. Our services are then ordered by the sites through physician orders on a patient-by-patient basis.

CEOCFO: Looking at your website it seems that you have had experience in almost every area of medicine but are there areas that you like better or that work better with your model?

Ms. Adinamis: I think that our service model is particularly helpful in oncology and rare diseases. Rare diseases affect less than 200,000 Americans a year and these patients typically do not reside close to the centers of excellence or the investigator sites. Many times they have to travel long distance by car or fly to the investigator’s site. Sometimes sponsors are paying thousands of dollars to relocate the patient and their family closer to the investigator site so they can participate for the duration of the trial. In this case we can cost effectively go to the patients, conduct study visits at the convenience of the patient’s home without them having to travel long distances or incur large travel expenses. There is a tremendous opportunity and benefit in rare diseases. The therapeutic area of oncology is very competitive. Sites have to recruit further and further away geographically to get patients into their trials. That challenge of distance can become an insurmountable obstacle for patients from even considering participation in a trial or in regards to compliance and retention. Oncology is also another large therapeutic area that we are heavily involved with. We are also very much involved with neurologic diseases where patients are somewhat debilitated and traveling to the investigator’s site is a challenge for the patients and their caregivers. GlobalCare’s service model can be employed across multiple therapeutic areas as well as age groups. Pediatrics or adolescents can have visits done prior to school which is a real benefit for them not miss school days.

CEOCFO: What have you learned over the course of your time in the industry that has been most helpful at GlobalCare?

Ms. Adinamis: We have been hearing recently a lot about patient centricity and having patients being the focus of trials. Historically the industry has been very good about creating sophisticated protocols but they have often lost sight that real people have to participate in these very challenging protocols. We really focus on taking care of the patient and making sure that we can make it convenient and comfortable for them. We try to address things that are important for the patients. That is why we are supporting clinical trials so that we help can get life enhancing products to market faster. Patients can really benefit from that.

CEOCFO: How do you reach potential...
customers?

Ms. Adinamis: What is interesting is that because I have been in the industry for over thirty years, so there are companies who have just come to me from knowing me in the past or I have been referred by former sponsors, sites or Key Opinion Leaders. We really have not done a lot of marketing to the industry in general because once we have established a client they become long-term clients. We have been adding one client at a time and showing that we can service our customers the way they need to be serviced. We have not needed to conduct any broad marketing effort at this point.

CEOCFO: How is business?

Ms. Adinamis: It is great! We are very busy and it keeps me up late at night and gets me up early in the morning.

CEOCFO: Are you able to handle as much business that comes your way or do you need to be selective?

Ms. Adinamis: Currently we are able to support all the business that is coming towards us and we are expanding globally. We have not been actively marketing because we have been indirectly selective on our clients. Our goal is to provide the highest quality customer service that we can and so our current clients get 100% of our attention. We have several long-term clientele for whom we have supported several studies now and we hope to continue to maintain that long-term relationship with them. We are getting demands for our services to expand into other parts of the world and clients that may have been domestic are now global clients so I guess we are expanding within our client base.

CEOCFO: Do you see much competition coming up?

Ms. Adinamis: What is interesting is that two of the competitors in the industry are actually companies that I started but I believe that competition is healthy and it helps to keep the quality up. I would imagine that anytime you have a good idea you are going to see competition appear and I would imagine in the next couple of years we will continue to see growing competition in this particular niche field. It is a very specialized field and it does require knowledge not just of clinical trials regulations but home healthcare regulations. The threat is that people will try to get into this industry who do not really understanding it and then provide services that may be damaging to the reputation of this type of model. There will be competition, but I hope that is quality competition.

CEOCFO: Why should the business and investment community pay attention to GlobalCare Clinical?

Ms. Adinamis: GlobalCare is the market leader. I founded the service model over twenty years ago and have established the foundation of the company on quality, standardization and customer service. We truly have a global network of exemplary resources in over 25 countries. Our country coordinators are generally private practice physicians or research nurses who are GCP certified and multilingual and our local services providers are typically skilled nurses. Our focus is on quality, customer service and of course the patient. We have a long list of very satisfying customers. We look forward to continuing to grow in this industry and we feel that the service is unique in that it provides a win/win for everyone including investors and pharma as well as the sites and the patients. We are able to demonstrate that trials can be completed in a shorter period of time with better compliance while making it convenient for everyone.

CEOCFO: Final thoughts?

Ms. Adinamis: GlobalCare offers an innovative service model that is not mainstream, but I do believe that it will change how we conduct clinical trials going forward. There is a push by FDA to pharma to find new innovative ways to conduct clinical trials to reduce the cost and the time to get important therapies to market and I think that this is one of those opportunities to help to achieve that mission.