

Symphony Clinical ResearchSM is helping Clinical Trial Sponsors Solve Enrollment and Retention Issues, which Increases Investigator Satisfaction while Lowering Costs



**Healthcare
Clinical Trials
(Private)**



**Ms. Nicki Norris
Chief Executive Officer**

BIO: Nicki is an accomplished senior executive with more than thirty years of experience in healthcare and healthcare services organizations. Currently, Nicki is the CEO of Symphony Clinical ResearchSM— Orchestrating Trials in MotionSM, formerly

known as Clinical Resource Network, LLC. Symphony is a small, high-growth equity-backed company, providing in-home clinical services to patients participating in clinical trials. CRN takes study visits to the patients where they live, work or play, making clinical trial participation comfortable and convenient. This unique and innovative service offering is “changing the pace of clinical trials” by improving patient enrollment timeframes and by increasing retention of patients during a clinical study. Both the faster enrollment and the increased retention of patients lead to time and money for our pharma customers.

Nicki has significant P&L and general management experience. She has a proven record of business growth, turnarounds, operational process improvements, sales and margin gains, and executive team development. She has repeatedly demonstrated her ability to rally an organization to achieve extraordinary results. She has led three organizations: a high growth multiple site dialysis services organization, a highly regulated, large blood services organization, and a major “gold standard” professional laboratory quality improvement business and laboratory accreditation program. Early in her career, Nicki spent almost twenty years with Baxter Healthcare Corporation, where she was able to develop her experience in almost every key functional area: strategy, planning, finance, operations, marketing, sales management, process improvement, change management and R&D. Her experience spans manufacturing, distribution provider healthcare and clinical research organizations.

The University of Illinois at Urbana-Champaign granted Nicki a BS in Finance and an MBA. She later sat for and passed the CPA exam.

Nicki has resided in the Deerfield, Illinois area with her husband for more than thirty years.

Company Profile:

Symphony Clinical ResearchSM (formerly known as Clinical Resource Network, LLC) is the global service leader in providing in-home and alternate-site clinical services to patients in all phases of clinical trials. Since 2003, Symphony’s combined experience in clinical research, project management, nursing and homecare has delivered a superior experience for sponsors, sites and patients. By taking some trial visits to patients in their homes, we make it convenient for patients to participate in clinical trials. Symphony’s services significantly accelerate the pace of clinical trials by leveraging our extensive network of clinicians to increase convenience for patients. Symphony helps clinical trial sponsors dramatically improve patient recruitment, compliance and retention as well as increase patient and investigator satisfaction. In-home services can be used in all therapeutic areas, and patient populations from pediatrics through geriatrics. Symphony complies with ICH/GCP, IATA, privacy rules and other applicable regulations.

**Interview conducted by:
Lynn Fosse, Senior Editor**

CEOCFO: Ms. Norris, would you please tell us about the recent change of name?

Ms. Norris: It was one of those things that was a journey, not a destination.

We embarked upon redefining this company three years ago, and rebuilt all of our processes and systems. We dedicated ourselves to providing quality service in compliance with good clinical practices. We have dramatically improved how we are doing things and the results we're getting. We got to a point where we felt we had reached completion and it was time for a new name to memorialize that redefinition. We decided that Symphony Clinical ResearchSM, Orchestrating Trials in Motion, represented the quality we provide and the way we provide our services. Like an orchestra, we bring together "virtuoso's" or experts in various different areas to coordinate seamlessly within an overall clinical research study and produce an outcome that is more effective than each of the individual parts. So, we decided to change our name as the final stage of redefinition, to our new more representative and descriptive name.

CEOCFO: Why the decision to change the focus of the company?

Ms. Norris: It was not necessarily a change in focus; it was doing things better. I think often little companies start out, their processes are not really mature, and the metrics for ensuring that the processes are working as desired are not everything they can be. We set out to really make this a quality performance company and we were able to do that.

CEOCFO: Who is using your services and what specifically are you providing?

Ms. Norris: Within a clinical trial, we take some of the trial visits to the patients in their homes. What you may or may not know about clinical trials or clinical research is that the biggest issues today are getting people to participate in a clinical trial. The issue with enrollment, which can be as low as one to three percent in oncology trials, and the issue with retaining subjects in these studies cause just huge wastes of time and money for the sponsor companies. Therefore, what we do is integrate our in-home services, making it convenient for people to participate in a study. It is

no surprise they are more willing to participate when things are easy and convenient for them, which helps that enrollment issue; and, they stay in the trial because it is easy and less disruptive to their lives. Solving enrollment and retention issues means time and money for the study sponsor. Our decision-maker is anyone who is responsible for managing a clinical trial, which can be a pharmaceutical company, a biotechnology company or a clinical research organization (CRO). We sell to whomever is managing a clinical research study.

CEOCFO: Is it becoming more common to work with people at home; is it something unique that you are offering and does it take convincing for the people generating the study understand your solution?

Ms. Norris: Yes, working with people at home within a clinical trial is very unique; it is an innovative solution. This is an industry that is heavily

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regulated and so people are very committed to making sure that whatever they do in their clinical research will be acceptable to the FDA and other regulatory agencies. I would say, relative to other industries, this particular niche in the industry is slower to take action, due to those regulatory concerns. That being said, the industry is facing some problems that they have not been able to overcome; in particular, enrollment and retention issues. These problems cause them to spend, on average, more than a billion dollars and more than ten years to get a drug on the market. The industry is trying many different solutions: outsourcing to CROs; using healthcare databases to identify patients more readily; using social media to identify patients; and this is another one of those concepts that should provide a solid feasible solution for these major issues.

CEOCFO: What are the biggest challenges in working on the outpatient

basis or working with the patients at home as far as maintaining the quality of the data?

Ms. Norris: I would say that the biggest challenge is attention to detail. What we have to do is understand clinical research, home care, nursing, and project management. We have to combine all those skill sets and then really study a protocol to anticipate where the risks are and put strategies in place that can mitigate those issues.

CEOCFO: Can you give me a concrete example?

Ms. Norris: When our nurses go into the home, they typically have a kit that is usually prepared by a lab ahead of time and it is used at the clinical research site to draw samples from the patient. We receive that same kit. However, before we take that into the home, we try to anticipate what can go wrong. In the home, the nurse does not have the same access to supplies that he or she would have at the research site. Therefore, if we think that they could use an extra needle or two or that they might need some cotton pads or perhaps an extra balance tube or a couple of extra vacuum tubes, we add those supplies. The last thing that we want is that they lose the samples from the visit because of the supply shortage or a supply malfunction. We try to anticipate those issues based on our expertise and take steps to make sure that the samples are collected successfully the first time.

CEOCFO: What are the special traits you look for in home technicians?

Ms. Norris: When you start thinking about clinical research, you start thinking about someone who is very data-oriented with high attention to detail. We certainly need that because ultimately we need to make ensure the protocol requirements are met to the letter. However, when you start talking about a real live patient, you need very high interpersonal and customer care skills, usually found more on the nursing side of things. We need to bring those all together with our corporate staff, where we need project managers who under-

stand how the process works and where the proper checks in this process are to make sure that things happen where, how and when they are supposed to.

CEOFCFO: Is there a specific geographic range in which you work or are you able to do this in a wide range and get teams together in a variety of places?

Ms. Norris: We work in about fourteen countries right now. We provide our service, certainly in the US and Canada, but also many countries in Western Europe, some Eastern Europe, Israel and Australia. We are always open to working in new countries, as long as we can maintain the highest standards of care.

CEOFCFO: How have your potential customers learned of you and how do you continue to reach them?

Ms. Norris: That is the billion dollar question. Over and over again we have customers tell us that they wish they knew the service existed. We speak at conferences, write papers, advertise and it seems, do everything to get the word out there. But, still, this is one of those things that people have not necessarily heard about. Typically, what happens is a major pharma company or CRO has a study that has a patient population, which for one reason or another, is immobile. They have rheumatoid arthritis, they are burn patients, transplant patients, mothers with little kids where the kid has to go to school or they

have other children, or they are dementia patients who get disoriented when they leave familiar surroundings, they need to drive into the city, and they are just not able to do that. You find that one of these companies has a research study and they are just having a terrible time with, so they come to us for what we call a "rescue" study. We come in and provide our services and they find out that by making it convenient, things go much smoother. Then that clinical team tends to use our services going forward because they know this works for a given population. Then, that therapeutic area clinical operations team will talk or move on to another therapeutic area. They will take the knowledge of our services with them; and they will see somewhere else our services make sense and word will spread that way.

CEOFCFO: How is business these days?

Ms. Norris: Things are going well. As you know, the population is aging and the need for drugs is everywhere. We are very tiny in the overall research world, so there is extensive room for growth. People are opening their eyes when they have a real problem, and they are seeing us an innovative way to meet that need and solve those problems.

CEOFCFO: Back in April, you added to your business development team. Are you still adding or is your team basically in place?

Ms. Norris: Actually, we have one more position that we are trying to fill and we are continuing to search for the proper west coast candidate.

CEOFCFO: We speak with many biotech companies, CROs, and we have about 200,000 readers in the investment community. Why should people pay attention to Symphony?

Ms. Norris: People should pay attention because most of us and our families take drugs. We need to make sure that those drugs are safe before they get into the overall population; clinical research is how you do that. An effective clinical trial tests the drug on a population that is similar to the populations that will ultimately be using that drug. Therefore, it behooves all of us to make sure that people are participating in clinical trials and that the test patient population is similar to the actual population where the drug will be used, so there are no surprises. Doing all of this is difficult if you do not have a population willing to participate in clinical trials; that is what we are experiencing today. By including in-home clinical services in your trial, you can make it easier for someone to remain in control of their lives and at the same time give back to the overall community by allowing themselves to be studied in terms of their reaction to a drug or a device.

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