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“In a late phase clinical research we must represent ourselves as an ambassador of [our client] and represent the pharmaceutical company with enthusiasm and pride. We strive to become an extension of the company as opposed to a contractor working in isolation.”

-Nayan Nanavati
VP, Peri-Approval
Clinical Excellence
PAREXEL

Executive Interview: Nayan Nanavati, VP of PACE at PAREXEL

Recently, **Q1 Productions** had the opportunity to sit down with Nayan Nanavati, the Vice President of Peri-Approval Clinical Excellence at PAREXEL International to discuss the impact of Phase IV Clinical Research on the pharmaceutical industry, the trends and recent successes with the utilization of CRO partners, as well as the growth and development of this dynamic organization. For more information about PAREXEL, visit their website at www.PAREXEL.com; or come out and meet them at the upcoming Phase IV Conference taking place this July 24-25 in Philadelphia.

Q1 Productions:

There is a tremendous discussion currently underway in the industry relating to increased post-marketing surveillance and the need for continued safety studies, often as mandated by the FDA. How do you think that the industry is adapting to these changes, and what new approaches are being taken to complete their peri-approval studies under heavy public and regulatory scrutiny?

Nayan Nanavati, PAREXEL:

It is generally well understood that registration or pre-marketing studies trials do not have sufficient statistical power to detect rare but serious Adverse Drug Reactions or common delayed drug reactions. Usually, these types of studies can only detect the most common adverse events. It is not until a drug enters the market and hundreds of thousands to millions of patients in a “real- life setting,” individuals who may be older, younger, of different ethnicity and genetic variation, have multiple co-morbidities or take medications or eat foods excluded in the phase II and III trials, are exposed to it that rare or delayed events are detected. This large group of people includes individuals who may be different than the controlled populations studied in the pre-marketing trials. In addition, they may be prescribed the drugs by their physicians for “off-label” conditions or may be noncompliant in drug dosing specified by the package insert/label.

In the recent past there have been several high-profile market withdrawals of several popular, approved drugs. It has been alleged that some pharmaceutical companies may have neglected clinical study results that indicated safety concerns for those products and failed to investigate them further. Such news and reports have generated tremendous discussions in the industry relating to the increase in post-marketing surveillance and the need for continued safety studies. The FDA now routinely mandates such studies as part of the product approval process. Many pharmaceutical companies are now voluntarily committing to conduct or initiating post-marketing safety and surveillance or experience studies.

I certainly believe that pharmaceutical companies are now better recognizing the value in carrying out such post-marketing studies. With the added demands from regulatory agencies, pharmaceutical companies are also rapidly adopting to these changes. Although the progress is a bit slow, as recently reported by the FDA, progress is being made. Here at PAREXEL, we are seeing more and more requests from the industry to help design or execute post-marketing safety and surveillance studies.

Q1 Productions:

Partnering with CROs has become a business strategy utilized by many pharmaceutical research and development teams as they work to complete their clinical studies as quickly, and as close to on budget as possible. What do you see as being some of the key advantages of a partnership with a CRO, and with PAREXEL specifically?

Nayan Nanavati, PAREXEL:

A recent study conducted by the Tufts Center for the Study of Drug Development which was commissioned by the Association of Clinical Research Organizations (ACRO), found that sponsors who are more extensive users of clinical research organizations tend to complete projects faster, while maintaining quality. At a time when bio/pharmaceutical companies are redefining themselves and delineating their core competencies, even greater emphasis is being placed on the ability to form meaningful provider relationships.

As it relates to Late Phase research, partnering with CROs has clearly been the business strategy utilized by many pharmaceuticals and bio-technology companies. Conduct of large late phase studies require core competency, integrated infrastructure and technology, and a very non-traditional mind-set of clinical monitors to work with naïve participating physicians. Many pharmaceutical companies find it cost effective and beneficial to outsource these late phase studies as opposed to creating the needed infrastructure and building the essential core competency.

PAREXEL continues to effectively support our clients in early as well as late phase research, whether it is through our consulting and advisory services, excellence in clinical research, technology products and services, or medical communications capabilities. For nearly 25 years, PAREXEL has been at the forefront of making the clinical development process more efficient and effective for our clients.

A decade or so ago, clinical research was pretty much confined within the boundaries of North Americas and parts of Europe. In today’s environment, clinical research has no boundaries, and is expanding in all parts of the world. PAREXEL has created a global platform that allows us to provide our clients with the best possible geographies for their programs.



Q1 Productions:

PAREXEL has worked with most of world's top 50 bio/pharma companies on the development and launch of many of the most successful therapies on the market. Share with us a success story of one of your clients.

Nayan Nanavati, PAREXEL:

PAREXEL has many success stories in working with our clients to share our expertise and make a difference in their businesses, with the shared goal of preventing and curing disease and getting important products into the global marketplace and to the patients who need them.

In one example from our Peri-Approval Clinical Excellence (PACE) business, part of our Clinical Research Services, we managed an expanded access program for a global pharmaceutical company, involving centralized management of more than 3,000 physician sites across 75 countries, which enabled 32,000 patients with cancer to receive a beneficial new treatment as quickly as possible. Through this expanded access program we were able to provide a break through and innovative drug to so many patients around the world.

Q1 Productions:

One of the greatest assets of your organization seems to be a diversified portfolio of products and services, enabling life science organizations the ability to work with your organization throughout the lifecycle of the drug development process. What are some of the synergies among these services that you have developed to provide more comprehensive solutions to clients?

Nayan Nanavati, PAREXEL:

PAREXEL has been effective in integrating our clinical development knowledge and technology expertise in order to help clients improve the speed and efficiency of their development programs. We have also identified new opportunities to help clients succeed in the marketplace by further combining our consulting and medical communications services, as marketing becomes increasingly integrated with scientific and regulatory considerations even earlier in the drug development planning process.

Q1 Productions:

What specific skills do you feel you were able to bring to PAREXEL after having worked within the Pharmaceutical Industry? Do you feel that your experience working on the sponsor side of the business prepared you for working within a CRO?

Nayan Nanavati, PAREXEL:

Having worked within the pharmaceutical industry for over 15 years, I fully understand the need to outsource clinical trials, and the value it brings in clinical drug development. During my tenure with the pharmaceutical industry I personally outsourced a variety clinical programs. I fully understand why pharmaceutical and bio-tech companies outsource their trials. The industry outsources their work because they need well trained man power, a special skill set, or a CRO partner that can help them expedite their development program. They expect a CRO partner to protect and maximize return on their costly drug development investment. The greatest skill set that I bring to PAREXEL is just that – a better understanding of our partners' need. This fundamental understanding of the core values associated with outsourcing paradigm has allowed me to be prepared to work within the CRO industry.

As a leader of the Late Phase Clinical research group at PAREXEL, I try to instill the same values and understanding within my unit. We routinely remind ourselves that we are a partner of a company we are working for, and it is our duty and obligation to protect their investment and maximize the return on their investment. In a late phase clinical research we must represent ourselves as an ambassador of their product and represent the pharmaceutical company with enthusiasm and pride. We strive to become an extension of the company as opposed to a contractor working in isolation.

Q1 Productions:

As a senior executive of a multi-national organization, you must spend a lot of time traveling – how do you find a balance between your professional and personal goals?

Nayan Nanavati, PAREXEL:

Being on the road is the norm, indeed. I travel as much as 40% of my time. It is so easy to get wrapped up in a daily work routine. No matter where I am in the world I find time to call my wife and my son at least two to three times a day. It is important to me to keep in touch with them. When I am not traveling, I do my best to spend quality time with my family after work. A meaningful balance between professional and personal goals is very important to me. PAREXEL as an organization strongly promotes the value of work and family life balance, and truly provides means to achieve the balance between work and life.