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Ramita Tandon
Director of Project Management
PAREXEL

Executive Interview: Ramita Tandon, PAREXEL

Q1 Productions recently had the opportunity to sit down with Ramita Tandon, MPH, the Director of Project Management at PAREXEL, regarding industry trends and movements as related to patient registries and post-marketing studies. For more information on PAREXEL and their array of solutions available, please visit their website at www.PAREXEL.com.

Q1 Productions: The industry currently appears to be vacillating between continued post-marketing studies, utilizing patient registries as an alternative, or fulfilling post-marketing commitments through a blend of both methods. What do you see as the driving trend to meet these regulatory commitments?

Ramita Tandon, PAREXEL: In recent years, we have seen the FDA’s increased demand and compliance tracking on bio/pharmaceutical companies to conduct effective and timely post-marketing commitment studies (PMCS) result in a commensurate increase in the dialogue on how the requirements can be cost effectively met. An observational design is often a practical and cost-contained choice to bring clarity around longer-term safety data and adverse events in a real-world setting, for example. At PAREXEL, we are seeing more patient registries being added as part of the post-marketing portfolio. Patient registries are useful for collecting outcome information not available in large automated databases and when information must be collected from multiple sources. Further, patient registries are now being viewed as means to fill an important niche between clinical trials and the current market dynamics of a product, device, or disease state.

In parallel, the FDA and the public have also stepped up demand for improved risk assessment, reflecting the growing concern about drug safety and it’s monitoring in the post-approval environment, as well as the need to more effectively investigate safety signals for approved drugs. Few disagree that this evolution will continue and represents the future of our approach and work on a product in its post-approval phase of its life cycle. Monitoring capacity for industry post-marketing commitments is anticipated to increase as further encouraging industry to formulate and implement their own risk management plans.

Perhaps as evidence of that evolution, we are seeing more requests from our clients to help design or execute post-marketing safety and surveillance studies, including patient registries before being officially requested by the FDA. I believe this is certainly a sign of bio/pharmaceutical companies taking the necessary time to proactively design post-marketing studies as part of their overall risk management plan

Q1 Productions: Partnering with a CRO is a business strategy that many organizations gravitate towards as they look to implement a first time registry, or continue to maintain an already existing registry. What do you see as some of the advantages of working with an outside partner rather than handling these activities in-house?

Ramita Tandon, PAREXEL: Contract research organizations play a vital role in each of the key stages of drug development to commercialization; through providing services to the pharmaceutical, biotechnology, and medical-device industries, CRO’s allow their clients to manage product-development efforts more efficiently and cost-effectively.

Clearly, bio/pharmaceutical companies are focused on growth and competitive advantages which can be made possible through strategic CRO partnerships. The next decade will realize the enormous opportunity for different forms of partnering due to increasing pressure on bio/pharmaceutical companies to contain rising drug development costs as revenue growth decelerates due to market competition, pricing pressures and the loss of large patent-protected sales. Such strategic partnerships allow for pharmaceutical companies to realize benefits such as in-depth experience and resources, technological skill, speed to completion for clinical programs, a ready made infrastructure of global research personnel is particularly appealing to bio/pharmaceutical companies to avoid bearing the costs of supporting a clinical infrastructure to meet the needs of an oscillating pipeline.

As it relates to late phase research, partnering with CROs has clearly been the business strategy utilized by bio/pharmaceutical companies. The conduct of post-marketing studies like patient registries require a core competency and very non-traditional mindset to achieve both the scientific and commercial objectives that are infused in such a program. A well-designed registry has the ability to serve as a powerful tool to obtain real-world data, including adverse events in various patient populations that go beyond the limited confines of controlled trials.

Here at PAREXEL, we are acutely aware that post-marketing studies are a critical element of the product development process, and that such studies come with particular and distinct complexities and challenges. As part of our clinical research services, PAREXEL’s Peri-Approval Clinical Excellence (PACE) business continues to support our clients in late phase research and provides bio/pharmaceutical companies with the crucial link between R&D and commercialisation through the application of experience.

Q1 Productions: In working with many of the Top 50 Pharmaceutical and Biotechnology organizations, you have certainly helped to identify new, potentially life-saving products that are now out in the market. Recent publications, however, have noted increased scrutiny from FDA might delay the widespread approval of new products. As an organization, how is PAREXEL helping their clients to navigate these regulatory hurdles – and are registries a component to this success?



Ramita Tandon, PAREXEL: From unmet medical need to marketable new product, PAREXEL helps bio/pharmaceutical companies to navigate through the increasing regulatory challenges by working to develop a strategic plan that takes into account the inevitable twists and turns of product development. PAREXEL is not simply a CRO that has a comprehensive toolkit of services, but we offer to our clients the knowledge of what tools to apply at which points during the various phases of the strategy development and commercialization to help our clients achieve higher productivity levels in a shorter timeframe with improved returns on investment. Additionally, the integration of the appropriate technologies in our clients' programs can enhance the effectiveness and accelerate decisions and processes associated with the development and launch of new products.

As the consideration of registry studies as a vehicle to collect more safety data grows, this type of post-marketing study offers value both at the pre-approval state in assessing baseline clinical practice patterns and optimizing the initial approach to market, as well as in the post-marketing stage, where strategies must be continually adjusted to address real-world responses. To that end, our Peri-Approval Clinical Excellence or PACE business unit continues to see our clients reach out to us to act as consultants in the design and implementation of such programs. Such partnership allows for our clients to realize the benefits of understanding the regulatory landscape but still design a program using a very non-traditional approach that serves as a platform to supplement data, such as drug safety, in a cost-effective manner.

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?

Ramita Tandon, PAREXEL: Our clients do express finding value in "one-stop shopping" with PAREXEL. The manner in which they view or procure across a diversified product offering is not confined, however, to outsourcing programs that are comprised of studies across the pre- and post-approval phases of clinical development, but includes procuring a turnkey product that is comprised of study management, technology and regulatory services under a single roof.