

Interview with Mariapia Cirenei, General Manager, Parexel International Italy



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Over more than 25 years, PAREXEL has expanded its global footprint through a combination of organic growth, alliances, and acquisitions. What was the rationale behind entering Italy in 1995 and which opportunities does the local environment provide to the group?

The high number of clinical trials conducted in Italy every year has been a key factor in attracting leading Contract Research Organizations (CROs) such as PAREXEL to have a presence in the country. With Italy's place in regional and international trials, it will surely remain a country of most importance for global CROs in the future. Indeed, according to Clinical Trial of Drugs in Italy published by the Agenzia Italiana del farmaco (AIFA), more than 700 studies were conducted throughout this geography in 2007. Most of these were part of regional or international trials.. In addition, Italy was the 6th European country in terms of amount invested in the pharmaceutical sector in 2007; and the 5th for the number of R&D employees, directly following the United Kingdom, France, Germany and Switzerland. Of course, the last Ministerial Decree published on March 31st, 2008 about the Definition of the minimum requirements for CROs conducting clinical trials on medicinal products, is modifying our work environment. But it is worth mentioning that PAREXEL's global standards have always been extremely focused on the same quality requirements that have now been made mandatory by law. Therefore, no changes will have to be implemented in the way PAREXEL carries out its activities in Italy.

What things of your previous experience did you choose to apply when taking the reins of PAREXEL's location in Italy?

PAREXEL's Italian office opened in 1995, with two employees. Today, 14 years later we have more than 140 employees in Italy, and have gained a strong position as one of the leading global CROs present in the country. I became General Manager of PAREXEL's Italian location in 2003, five years after joining PAREXEL. I previously developed a biologist background followed by a long experience in an international pharmaceutical laboratory. Joining PAREXEL was an excellent opportunity, which enabled me to change activity while remaining in the biopharmaceutical industry. Indeed, many similarities can be found between pharmaceutical companies and CROs and at the end of the day, the goals are the same: both types of organization are committed to bringing new treatments to the market to the patients who need them, in the safest, quickest and most qualitative way possible.

How do you assess PAREXEL's recent performance in terms of growth and revenues?

In Fiscal Year 2008, PAREXEL increased revenue growth by 30% over the previous Fiscal Year to \$964.3 million U.S. dollars. PAREXEL's office in Italy contributes to overall geographic revenue; for Fiscal Year 2008, PAREXEL's Europe/Middle East/Africa region represented 54% or \$515.4 million of total service revenue.

And as faster growing regions such as Latin America, Central Europe and Asia Pacific seem to be a main focus of PAREXEL at the moment, to which extent is Italy still a priority for the group?

Italy is and will remain a priority, for the simple reason that it counts amongst the most important pharmaceutical markets worldwide. Indeed, on an annual basis the pharmaceutical industry's spending in Italy was 16,693 million Euros in 2007 (following the US, Japan, France, Germany and UK). This represented 3.2% of worldwide spending, and therefore this is indicative that excellent opportunities for clinical development are being generated in Italy. It is surely in the interest of both local and international pharmaceutical companies to make sure the country is covered by their clinical research departments. While PAREXEL has a strong presence within Italy, representatives in Italy are extremely proud to be part of a truly global company, which has 71 offices throughout 51 countries and more than 9,250 employees worldwide. This global presence allows for a comprehensive understanding and a deep overview of the global market trends in clinical development and the needs of various stakeholders in the clinical development enterprise including sponsors, investigators, and patients.

Yet isn't there a need to adapt such a global strategy to the local specificities- and in this case, the Italian environment?

Of course, bringing its global vision into a wide range of different countries, the organization also has to adapt to each market's specific needs. For instance, regarding the business model developed in Italy, PAREXEL decided to have one single centralized office, despite the healthcare system's de-centralized organization. Such structure enables PAREXEL to better harmonize the teams and deliver face-to-face training as well as other advantages that provide clients with PAREXEL's ability to manage complex programs on a worldwide scale. PAREXEL has worked with regulatory authorities throughout the world, and has conducted more than 14,000 studies with over 36,000 investigators in 97 countries, including Italy. Such combination of strength and flexibility granted PAREXEL the trust of the top 10 global biotechnology companies and the top 20 global pharmaceutical laboratories, as well as hundreds of small and emerging biopharmaceutical companies.

What added-value can PAREXEL bring to their product development?

Over more than 25 years, PAREXEL has concretely demonstrated through proven results its expertise and ability to bring added value to its customers. PAREXEL provides deep expertise and capabilities in product development and regulatory affairs consulting, clinical research, eClinical technologies, and medical communications. In fact, PAREXEL has helped to support the development of nearly all of the 50 top selling drugs on the market, and has helped drive the success of thousands of its clients' development programs. A key goal of PAREXEL's local office locations is to rely on the strengths of an international company, yet manage studies locally and take into account the needs of each client to offer customized solutions. For instance, whereas PAREXEL's office in Italy is mainly focused on supporting late phase clinical development – namely Phase III, Phase IV and post-marketing observational studies, for which the country is more renowned- it can also rely on the Company's global capabilities to provide the early phase clinical development services.

In a context when the industry is strongly looking for cutting edge technology, how does PAREXEL manage to remain one step ahead and constantly upgrade the level of expertise of the solutions developed through Perceptive Informatics, in order to remain a preferred partner for its customers?

PAREXEL is increasingly meeting client demand in Italy, and worldwide, to obtain clinical and technology capabilities from a single source. With mounting pressure on the biopharmaceutical industry to improve product development processes, PAREXEL brings together clinical expertise with the industry-leading eClinical technology capabilities of its technology subsidiary Perceptive Informatics to help clients increase the efficiency and productivity of clinical studies. In August 2008, PAREXEL completed the acquisition of ClinPhone, a clinical technology company, which made Perceptive Informatics the industry's leading eClinical solutions provider. Chief among these solutions are Perceptive Informatics' Interactive Voice and Web Response Systems (IVRS/IWRS)

a, which manage important clinical trial functions, including patient enrollment and randomization as well as study drug inventory management. PAREXEL has a track record of providing EDC-driven solutions for more than a decade. Perceptive's EDC solution is a key component of its integrated eClinical platform, allowing for even more effective information flow across the various functions and organizations that are involved in clinical development. Another key component of Perceptive's eClinical portfolio are Clinical Trial Management Systems (CTMS). These centralized systems orchestrate operational and administrative activities to manage clinical trials. Perceptive also provides Medical Imaging, which is increasingly used as a surrogate endpoint or biomarker to assess safety and efficacy of new compounds, accelerate development, and decrease the cost of getting treatments to market. Perceptive also provides Electronic Patient Reported Outcomes (ePRO) solutions, and integration and implementation services. Aside from these competitive advantages, image building is also critical to fuel a long-term growth.

What does PAREXEL stand for in Italy and where do you see further room for improvement in terms of brand recognition?

Indeed, not only is PAREXEL recognized as a preferred partner by its customers, but is also respected by the national authorities, who recently invited representatives from PAREXEL's office in Italy to participate in the technical meeting at the Italian Agency AIFA – Clinical trial Unit with pharma company representatives, non-profit institutions sponsoring trials, and Ethics Committees. An outcome of the meeting included a project that AIFA would perform with our collaboration in order to improve the Italian electronic system for management of clinical trials from the regulatory point of view., focusing on an 'Osservatorio version' for the e-submission and e-approval of clinical trials in Italy.

Looking at human capital as another main growth driver, how does PAREXEL attract and retain the best talent, with the necessary local expertise and knowledge of the market?

With PAREXEL's reputation, we are able to attract the best talent in the Italian market. In terms of retention, it is worth underscoring that the company offers an excellent working environment as well as considerable opportunities in terms of career development.

What are your ambitions for PAREXEL's office in Italy in the next three to five years?

In the next years, PAREXEL's office in Italy will continue to work in the same high quality and customer-focused way. We will continue to work as a dedicated partner to our clients, offering the full-spectrum of services, and seamlessly integrating our global capabilities, expertise, and technology solutions to meet their needs. Our capabilities in Italy will continue to assist our clients in leveraging a wide array of geographies in order to conduct programs of any size, virtually anywhere in the world.

On a more personal note, what would you say is the best lesson you have learned from your career in the pharmaceutical industry, and which main obstacles did you have to overcome?

Joining the pharmaceutical industry many years ago, taught me how to be hard-working in every way, to contribute to a very important mission – bringing significant life-saving innovative treatments to current and future generations. AtPAREXEL, which has a mission to support the biopharmaceutical industry with expertise, experience and innovation to help prevent and cure disease, I was able to further this personal goal. I am proud to be part of a company and industry that includes so many women that are successful and recognized for their work and valuable contributions to advancing biomedical science. Overall, I personally believe that the key to succeed in this field is to choose the right pathway to develop your particular expertise, since we all share common objectives to help bring safe and effective treatments to patients worldwide.

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