

Interview with Lisa Becker, Global VP, Integrated Patient & Site Strategies and General Manager of Quintiles BV, Quintiles Netherlands

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ive, you seem to be fully integrated into the local community. Can you explain to our readers what brought you here to the Netherlands?



The quick answer is the charm of the Dutch. Perhaps more importantly, what's kept me here has been the opportunity to be involved in clinical research in its journey eastward. When I came to The Netherlands in 1989, clinical research was more established in the US. Through the biotech boom and beyond, multi-nationals came to appreciate the opportunities for development (through clinical trials) in Europe. Much has happened in the last 20 years to propel Europe to its rightful place as one of the established regions for clinical research. While there is a continued shift to the east, Europe will also continue to grow, and remains very attractive to companies developing products, devices and technologies, regardless of the company's base of operations.

We have heard mixed views on the clinical trials environment in the Netherlands. We are hearing of tighter regulations and more stringent reporting requirements, while at the same time the quality of research is perceived to be very high in the country. From the Quintiles perspective, how do you view the environment here? What does this market ultimately represent for Quintiles globally?

The Netherlands has traditionally been one of the best countries for medical care, due to the number of expert clinicians, a focussed public health policy and practice, good access to care, research/tech savvy population, and excellent networks for patient recruitment and specialist centres. By extension, it was also considered a good clinical trial country.

The Netherlands also has very good infrastructure in place for healthcare records. This facilitates access to important population data for sponsors, which makes feasibility and patient recruitment more streamlined.

Since the implementation of the EU CTD in 2006, the METC approval process has become more cumbersome and slow in the Netherlands. Before implementation, regulatory approval generally took between 30 and 60 days, whereas now, approval timelines are substantially longer. This makes the Netherlands less attractive as a location to sponsors of international studies with precise recruitment timelines,

To achieve the goal of healthier humans by getting new and better medicines to patients, faster, all stakeholders including policy makers, regulators, and sponsors should be working better together.

It has been said: There is a big difference between conducting clinical trials in the US versus Europe: in the US it is more about generating data, proficiency and efficiency, whereas here the context is more focused on the patient's care and partnerships. Do you agree with this statement?

The clinical trial industry is increasingly a global market and international companies must work in a consistent manner.

The data that is required to address the priorities of regulators must be collected regardless of where the research is being conducted

In the New Health Landscape there are more and varied stakeholders including providers, payers and of course patients. Improving access to health information has resulted in patients being more proactively involved in their own care, so they are certainly emerging as one of the key stakeholders. This is a priority around the world.

You have mentioned there is a clearly defined regulatory environment for the industry. Since 2006, the healthcare system has changed drastically in the Netherlands, which impacts Quintiles customers, as well as the efficiencies that you generate for your partners. What types of creative thinking has that engendered within Quintiles?

In the changing environment biopharma must demonstrate value, improve productivity, accelerate outcomes and overcome complexity.

The first step is putting the patient at the foremost of what we do. We need to focus not just on developing newer medicines, but better medicines. Sometimes this will involve adjusting the criteria for success in order to meet the varied expectations of multiple decision makers. Biopharma needs to respond to the specific needs of payers and delivering products that safely and reliably address critical healthcare issues.

Other solutions will include:

• Rethinking, resizing and restructuring the approach to discovery which will mean exploring outsourcing solutions that decrease infrastructure costs and convert fixed costs to variable costs; and

• Identifying partners who become allies. In other words, those who not only provide development expertise, but who are also willing to share in the development risks associated with new therapies.

In parallel, the biopharmaceutical industry must capitalize on opportunities, such as:

- o Triggered monitoring
- o Adaptive trial design
- o Advanced biomarker technology
- o Digital pathology
- o Data-driven patient recruitment
- o Active site management and
- o End-to-end trial management

There is a world of alliances, JVs, partnerships constructed to align interests and manage risks. How is Quintiles helping their customers to manage risks, efficacy and productivity of their trials?

The prevailing approach to accelerating outcomes is globalization which allows sponsors to trim years from trial times and ultimately introduce new generations of therapeutics more rapidly is globalization. Globalization is able to do this because it facilitates:

- Increased scalability of operations;
- The application of integrated solutions across multiple geographies; and
- Greater access to patients with diverse characteristics throughout more disease states.

However, biopharma needs to ally with other organisations in order to manage these risks and accelerate outcomes.

These strategic alliances will play a critical role in reducing the complexities today's biopharmaceutical industry faces. Complexities such as:

- New biochemical targets and the molecules required to address them;
- The medical conditions that require new therapeutic solutions;
- Emerging technologies and their applications;
- Management of the globalization of clinical trials;
- Variable definitions of quality

There are plenty of small Biotech companies in the Netherlands, many of whom do not yet have products coming out on the market but they have interesting potential. No project is obviously too big for Quintiles, but are there projects that are too small? How do you interact with and reach out to smaller firms?

Quintiles Netherlands is the Dutch affiliate of Quintiles which is based in the US. We are essentially here to carry up the Dutch arm of whatever international clinical trial we have, which are generally of considerable size, however we also conduct studies just within the Netherlands.

For smaller companies however, the value we can add is different. With Quintiles, the customer gets access to an ally with the ability to deliver, but also with the flexibility to adapt to the local market, and with the skills and expertise to optimize a program and develop the product. Quintiles is aligned with several science parks and is exploring ways to collaborate with the growing start-up community in The Netherlands.

It seems like a taboo these days to call a CRO a CRO, and there is a parallel shift away from that. Do you see yourself as setting the bar in redefining the concept, and introducing yourself as the next fully integrated service provider?

We would like to believe so. There is greater convergence between clinical and commercial across the product life cycle. The focus is on becoming more patient centric and treating patients unmet medical needs. A commercial mindset earlier in the clinical development process is therefore required and Quintiles is uniquely placed to help customers with that.

How do the skill sets and the mindsets of your staff collectively sum up to the corporate culture at Quintiles?

The overarching culture is a drive to progress care and outcomes for patients.

In the Netherlands, Quintiles has a young staff and is seen as a place where many frequently find their first or second job. Roughly 80 percent of our people have a university degree, while the average age in this office is around 28 years old.

Quintiles, and particularly this office, was voted the best place to work in the first year after launch. It is being said that the flexibility within Quintiles is something that makes us unique. Employees receive clear direction and have shared goals within the organization. Quintiles, as an organization, is also rather regulated. The company has a strong learning and development program, complemented by standardized operational procedures. The oversight focuses not only on compliance, but content, ensuring all staff have access to tools and resources to get their jobs done efficiently and with a constant eye on quality.

An example of how Quintiles aims to reinforce common goals within the organization is one of our employee engagement initiatives which essentially shows the individual's involvement in the entire process of clinical development. The interconnectivity this generates is extremely important because it makes clear why you as an individual person are important to our organization, and that when you execute, you also put the rest of the process into motion. This is a great way to achieve common goals.

Apart from flexibility, Quintiles also offers career development opportunities across the enterprise. Within the larger organization, we see vertical and horizontal moves as development opportunities, with the places occupied closer to the top by those who have gained a broad understanding of the business and functions within it.

What do you see as being this company's role in breaking new barriers?

Quintiles has conducted more clinical research than any other organisation, so is therefore well placed to help customers navigate the challenges of the new health.

In addition to the things I have already outlined, there is an increasing reliance on data-driven decision making at all points in the product life cycle. This is key in answering the questions of a wider range of stakeholders while simultaneously speeding products to market.

The Netherlands that relates itself more to Scandinavian countries, surprisingly has few women in top management. What is your perspective as a semi-expat in top management?

I believe that across industries more effort should be spent on driving and supporting more women in top management. A contributing factor to the inequality is the difference in work-life balance men and women maintain along their career path.

For me as a female with American roots, this country provides a unique set of challenges, but it also provides great exposure to different culture and different people. To truly pioneer within the industry, you have to be open and resilient to change, and you have to lead those changes as well.

I truly believe that the leadership opportunities that have been open to me as a female are available for everyone, male and female alike.

We would like to ask you for the final message on behalf of Quintiles to sum up the whole interview to the readers in the Netherlands and to the international community.

Quintiles is working hard to become the clinical development partner of choice, both globally and locally, with excellent quality, data integrity, and a positive patient experience at the core of everything we do.

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