

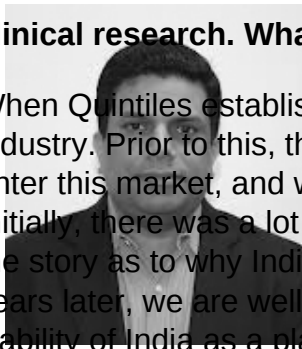
Interview with Anil Raghavan, Country Head Quintiles India

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When did Quintiles establish its operations in India in 1997, which was a very early stage in clinical research. What have been the main changes undergone by the country since then?



When Quintiles established operations in India in 1997 via a joint venture, it redefined the CRO industry. Prior to this, there was not much CRO activity in India. Quintiles was essentially the first to enter this market, and we paved the path for the rest of the industry.

Initially, there was a lot of persuasion involved to bring our customers on board. We needed to sell the story as to why India was a promising destination in which to conduct clinical research. Now, 14 years later, we are well past that stage. I think that today global pharma clearly recognizes the viability of India as a place for conducting research.

The regulatory framework in this country has changed significantly since those early days, and we are very proud of the fact that we have contributed to this evolution towards a more robust regulatory pathway. India has a fairly good architecture right now from a regulatory standpoint, especially for later stage clinical trials.

We have also seen tremendous developments in the Indian economy over the last two decades, which has had a very positive impact on not only healthcare infrastructure, but also on general infrastructure. From airports to roads, we have seen dramatic changes in this country over the last fifteen to twenty years. Given the more robust regulatory framework and these positive economic developments, we are now in a situation where India essentially sells itself as a prime location for drug development.

Some of your peers in the industry tend to think that India has not yet reached this level of maturity. There are still concerns over IP, quality, and the regulatory framework is still being defined, as the government has a very cautious approach to clinical trials compared to other Asian governments where the will to become a clinical trial hub is high on the national agenda. So, in your opinion, is India mature enough?

Yes, I think so. First of all, I would like to say that we are very supportive of the DCGI's (Drugs Controller General of India) approach. Quintiles has experience across multiple emerging markets, and we have seen this learning curve being played out. When a country steps up the volume of research conducted, that country's regulatory apparatus needs to evolve along with it. We see this as a natural and positive evolution of the regulatory environment, so we don't have concerns about the direction the DCGI is taking. There has been a fair amount of support from the government to develop India as an innovation hub; in fact, it is a stated priority for India.

Are there things that could be done differently? Of course, but that's the case anywhere. There

are concerns about site quality, but they are very different from the kind of concerns we used to have when we started out in 1997. Before, the question used to be, “Can we do a trial in India?” Today it has become, “Are we doing too much in India, and can we handle such volume of activity?” This is again part of the maturing of the country, and that is very positive because players across the spectrum will tighten their process infrastructure in response, and the overall system becomes much more competitive.

In a nutshell, what would you highlight as the main competitive advantages of India compared to neighboring countries?

India is a very obvious place to conduct research. The healthcare system has evolved dramatically, and the quality of the investigator pool is a substantial advantage. There are currently more than 60,000 well-trained, English-speaking, computer-literate investigators in India. The proficiency in English language is a particularly clear advantage. Apart from consent-related materials, we don’t have to translate any other documents, which is a very different ballgame from the neighboring countries.

Also, the disease profile in India has changed over the last 10 to 15 years. Lifestyle diseases have become much more prevalent, and as the patient pool increases, India’s need to participate in clinical trials increases as well. In India, it’s not just a commercial incentive to emerge as an innovation hub; we also have a stake in the game to find solutions for conditions like heart disease, which is the number one killer in India. So, besides the access to investigators I mentioned earlier, these environmental factors also make India a competitive country for drug research.

One additional advantage of India is that the country is very competitive in a lot of peri-clinical services, which is not a natural strength of many other Asian countries. IT capabilities and the ability to process and make sense of data via analytics are both crucial in modern clinical trials. If you look at the composition of Quintiles’ revenue, approximately 30 percent comes from clinical trials, while 70 percent comes from data-related services, processing biomarkers, etc. These peri-clinical services are a unique strength of India, which is something that not many people know.

India only represents 0.5bn out of a 20bn USD CRO industry worldwide. How do you see this evolving, and how do you see the operations in Quintiles India contributing to the overall Quintiles group?

I will not mention any specific numbers about the industry, but I will reiterate my optimism about the future of this industry in India. The clinical trial environment will continue to mature, and we will continue to conduct, effective trials here with safeguarding patients at the center of all we do. We are also confident that this industry in India will continue to sustain its growth trajectory in the coming years. The main driver for the market is going to be those peri-clinical services I previously mentioned: data services, especially functional sourcing, markers, etc.

As to Quintiles India’s contribution, we are one of the largest operations in emerging markets under the Quintiles umbrella. Outside of the U.S., this is one of the only places where we have a full service offering. In terms of trials, which encompass the clinical development aspect, we offer a lab, cardiac safety services, data management services, pharmacovigilance, and a Phase 1 unit – which is a joint venture with Apollo Hospitals. So in terms of spread of services, this is as robust as it gets in the CRO space – and we will continue to expand in India.

Competition in India is on the rise, both from local Indian CROs who claim they have better local knowledge and from other international CROs who are ramping up their operations in the country. As the market leader, how do you see Quintiles’ positioning evolving?

Over the last couple of years, we have seen our peers growing or setting up their operations here, and we welcome this as a very positive development. Besides our spread of service offerings, we

have a number of additional significant strengths. Quintiles India has a staff of 1,700 people. That's the largest pool of talent in this industry, which definitely gives us a competitive advantage. We also have a fifteen-year head start in doing business in this country compared to the other players. We understand this place better than any of our peers, and that understanding extends beyond just the region itself; it translates to better relationships with investigators, key opinion leaders, and other service providers. The bottom line is that Quintiles has an ecosystem that is much more mature than the others. I am sure they will become very good operators, but it will take a little time.

Talking about being a pioneer, could you please elaborate on your partnership with Apollo Hospital?

We believe in the need to be closer to hospitals for Phase 1 studies. We evaluated our options in the emerging markets, and Apollo, as a world-class provider of healthcare services, was the natural choice. We have a pioneering presence in India from a clinical research standpoint, and Apollo has a vision that is fairly comparable. Their infrastructure in Hyderabad is really top notch. We are very proud to be associated with Apollo.

You have recently set up a data management center in Bangalore. As I understand, these services will drive the growth of Quintiles India in the future. Could you please elaborate on the ambitions for this center?

We got into data management in a significant way in 2003 and 2004. Unlike many of our large CRO peers, we had foresight that the industry would follow a BPO (business process outsourcing) kind of route and we were correct.

From a CRO standpoint, Quintiles has been a trailblazer in presenting a global delivery model for data management. As a result of this, we are probably the only viable data management operation in the CRO industry today. Our competition is mainly companies in the BPO sector, such as TCS and Accenture. We have a comparably sized operation as these companies in India, which works both in terms of delivery of project-by-project services, as well as delivery of large functional outsourcing needs where we actually set up dedicated units for some of our customers. We also have a robust comparative advantage to large BPOs because we bring the subject matter into context. We integrate the data management process with the clinical process, which is not something that BPOs can do. After going through the BPO experience, many big pharma companies now recognize the value of this closer integration.

Human resources are a major concern in India, as attrition rates are very high. How does Quintiles India manage this issue and retain the best talent?

Attrition rates have indeed gone up substantially. We work hard on being a great place to work, and according to surveys, Quintiles India is consistently among the top 50 employers in India across all sectors. We work closely with universities, and the amount of training we provide is incomparable. For someone looking for a holistic development experience, we offer the best package in the industry. We also have an advantage in the market because we provide international careers, which is desirable to many of our staff.

On a more personal note, you were working in the U.S. and decided to come back to India. What compelled you to take on this position?

I am very excited about some of the possibilities we have here. Quintiles has a robust foundation in India, which means we have an opportunity to contribute substantially as this country evolves and perfects its regulatory infrastructure. This is something I am passionate about, and Quintiles is dedicated to building this platform as well. We are very positive about India's potential, and we

feel that a lot of emerging markets can learn from the Indian experience of creating scale, perfecting the system and continuing to build and grow from there.

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