Interview with Bernadette Morris-Smith, Business Development Consultant, TranScrip Partners

05.12.2012

Tags:

TranScrip Partners

Senior Partner Dr Sree Haran has also participated in this interview.

TranScrip Partners is by now a well-established player in the UK but a new player in Asia Pacific. Would you begin by introducing TranScrip Partners to our readers?

Dr. Sree Haran: TranScrip Partners was founded in 2008, and differs from the traditional CROs in the sense that we are not directly involved in the running of clinical trials and in data management. We primarily provide consultancy services in drug development and cover the entire process from molecule to medicine: from translational medicine, clinical development, regulatory, and to the market place in terms of medical affairs support and product in the market place. The expertise brought together in TranScrip covers all these areas. I would like to highlight our expertise in some key areas such as pharmacovigilence, a key component in the current environment in providing risk management plans and safety updates for companies as well as in managing the global regulatory requirements of our clients

Dr. Morris-Smith: TranScrip Partners brings together one of the largest and strongest groups of pharmaceutical experts in the industry. Most of our partners have between 15 and 20 years of experience in senior roles in major pharma companies. We are not just a loose network of pharmaceutical consultants; we are a partnership that has all the elements of a company. For example we were audited by the MHRA just last year and are pleased to say that we came out without a single critical finding.

Dr. Sree Haran: In addition to covering the functional areas in pharmaceutical & drug development, we cover most, if not all, therapy areas. Most of our physicians are experts and certified specialists in many of the key areas â?? we probably have the best group of anti-infective experts outside big pharma and also have great expertise in oncology, immunology, respiratory, diabetes, CNS.
We work with 40-50 clients at any given time, many of which are top tier pharma companies, while we are also developing strong relationships with smaller biotech companies. We are strategic thinkers who do, and doers who think â?? this means that we do not just provide strategic consultancy advice but are actually involved in a lot of operational activities. Apart from running trials we work on a number of operational deliverables.

Could you speak as to why the Australian pharmaceutical industry would choose to work with newcomer TranScrip Partners with its strong European base?

Dr. Sree Haran: Firstly, if one talks to client as an Independent Consultant andthey ask for help on a matter that the independent consultant has no experience or expertice our Partners are now able , through TranScrip as a one-stop shop, to optimally meet the client needs utilizing the best experts in the industry, from people with long and impressive careers in the top layers of big pharma. We are one of the few organizations that put forward this model of senior people running a development consultancy at a global level. We want to focus on that as our unique selling point.

Furthermore, the reason for the declining R&D productivity in the global pharmaceutical industry is that we do not really innovate in late development. There is a feeling that innovation means focusing on discovery, on early development and proof of concept, but we, the pharma industry, have failed in innovating after that stage over the last twenty years.

For this state of affairs, all the stakeholders in the process, the regulators the pharma industry, payors and investors should take some responsibility. The environment is now forcing the industry as a whole to navigate to innovation, because it is clear that the traditional way in late phase development will never address the lack of R&D productivity.

TranScrip Partners offers that extra value-based look at clinical strategies so that we start changing the paradigm â?? working with regulators and looking at different end points that are much more patient oriented. At the moment we are working with a client on a type 2 diabetes molecule which is still in pre-clinical development. If we can take that molecule with a novel target and run a phase III program in type II diabetes, we know it will not come up with an outcome that is any better than existing agents. The only way that one can provide that differentiation is to look at diabetes, along the lines of what oncologists have done with breast cancer: change the paradigm of breast cancer such that it is no longer a single disease, and they have used molecule markers to do that. The industry has not done that in many other disease areas. TranScrip Partners feel that the time is right to help biotech companies to look at new developmental and regulatory paradigms and in this way we can add value over a traditional CRO.

Dr. Morris-Smith: The benefit of TranScrip Partners is that we have a broad overview of the industry, the pharmaceutical companies and biotechs, and know where they are at with development. When youâ??re in the middle, you cannot see the bigger picture. TranScrip Partners can come in and look at where the molecule is going and detect hurdles or potentials that the client might have not thought about because their focus can be deirected on the drug itself and sometimes the case, not the bigger picture â?? or they may not b aware of other potential. We understand that these products are very special to the company as if it is their baby, and we need to walk carefully through the development process with them.

From an outsiderâ??s point of view, one might be perceived as courting risk in an ambitious way, getting into the Australian clinical trial market at the present time, given the decrease of the number of trials we saw in past years. Can you explain the strategy behind this move?

Dr. Morris-Smith: In Australia we did see a drop indeed with the number today picking up again but still not above the 2007 number, whereas in the wider Asia-Pacific region the number continues to increase. The government is aware of this in Australia and is committed to establish the right conditions for the number of trials to grow further â?? Prime Minister Gillard recently published a new investment plan to boost the development of the Australian research industry. However while the number of trials may be decreasing going down, the number of innovators that are here are still increasing. Australia has always been and always will be a country of innovation. so to focus on the number of trials doesnâ??t actually describe what is really happening. Dr Sreeharan and I were only discussing this recently and he had some key insight.

Dr. Sree Haran: When I was European medical director at GSK, we had a discussion about the role of the UK within Europe that came to mind when we looked at Australia and Asia-Pacific. In the early 90s, the share of European trials in the total of trials within GSK globally stood at maybe 20 percent. The vast majority of the contribution in global trials came from the US. We received the mandate to increase the share of clinical trials conducted in Europe, for which we looked at a different role for the UK within the bigger European picture.

Over the next 5-6 years, , Europe increased its contribution to around 55 percent of the total global programs. Most of the expansion came from Central and Eastern Europe â?? 40 percent, and the UK contributed only 6-7 percent. The UK cannot contribute in terms of volume in Phase 3 trials because of its size, but it is a great innovative base from which to lead the expansion and to participate in â??high valueâ?• studies such as in translational medicine or Proof of Concept studies.. We expect Australia to play a similar role in our Asia-Pacific expansion collaborating with centres in India and China and providing both â??technical leadershipâ?• and contributing in the high value end of the clinical trial spectrum.

What lessons could Asia-Pacific learn from this European success story?

Dr. Sree Haran: In the mid 1980s, Europe was the little sister in clinical trials and was struggling to get trials approved in America on the basis of European data. This is no longer the case, Europe has come of age. we think the same thing will happen in Asia-Pacific and Australia. Many of the learnings we had in Europe can, with some modifications, be applied to Asia-Pacific.

One of the reasons for the European success was the cooperation that various European countries established with one another through both private and government structures.

Outside of my role in TranScrip I have a visiting professorship in Malaysia and Singapore, and on the advisory board of CONNECT, the South Korean network of clinical trials, a government sponsored organ. We should try and replicate the European networks in A-P, and we believe that TranScrip can help to develop that model. We feel that Australia is very keen to be part of setting up these networks. The number of trials in Australia might go down, but the role as an innovation hub and a place that delivers chairs of advisory boards and regional leaders through its academic groups can increase.

Australia in the Asian Century is indeed one of the key themes occupying the Australian mind today â?? would you speak in a bit more detail about how TranScrip will use the Australian operations as a possible springboard for further expansion into APAC?

Dr. Sree Haran: We, like many companies big and small, wish to establish ourselves in Asia-Pacific. At the moment our founding partner has just returned from a two-week trip to China as part of a Trade & Industry Mission. There are two ways in which we want to approach Asia-Pacific: one is from the UK, making use of the help that we get from the British Ministry of Industry and Trade.

The second string to our strategy is Australia. The model will be slightly different from the model of the UK in Europe described before. It is a wellestablished and a well understood model â?? many companies use the UK as an R&D hub to manage Europe. Australiaâ??s role in Asia-Pacific will be slightly different â?? I would call it a partnership model or a center of excellence model.

Our plan is to create the TranScrip Australia center of excellence together with another center of excellence on mainland Asia â?? we are looking at China or alternatives in its proximity. The role of Australia will be crucial as the office will work in close collaboration with the Asia office, bringing the same value as the UK brings to Europe.

Dr. Morris-Smith, you have a past as a specialized consultant in clinical research for Biotech Industry â??we see a lively Australian biotech industry with more and more companies reaching later clinical trials phases. What role does the biotech industry play in TranScrip Australiaâ??s strategy?

Dr. Morris-Smith: We feel that we can be of invaluable service in Australia working with smaller biotech companies to assist them in their drug development stages..

Australia shows excellent biologists & chemists that come up with molecules that could be taken into development. What they often lack is experience & expertise in terms of drug development and in terms of converting the molecule and taking it into humans and developing it to proof of concept.

TranScrip Partners has helped small companies in translational medicine to take their lead programs, write their clinical strategy and take it to proof of concept, and as part of that exercise we have helped companies to work with major pharma companies on business development.

If we were to come back in three to five years for the next edition of our report, where will you have taken TranScripâ??s Australia operations?

Dr. Sree Haran: In the first four years of TranScripâ??s existence we grew from four people to forty people. We are actually keen in the UK not to go beyond a certain number â?? we do not want to become a Quintiles or a Parexel but opt to remain a high-value company doing things differently from large CROs.

Our current strategy is not only to continue to sustain our growth, but also develop a globalization strategy. We have set up the Australia office, are looking at setting up an office in Asia, have just registered in the US, and are looking at other markets in continental Europe for an office â?? Basel, Switzerland or Brussels, Belgium for instance..

The mission for Australia is to grow in the first three years to a critical mass and develop both as a stand-alone entity that nonetheless will work in close collaboration with the UK and be part of the global Transcrip organisation We strongly focus on sharing resources rather than duplicating them â?? we will use UK-based expertise to provide advice in Australia and have also have executives with both local and global experience on the ground.

It is very similar to strategies that many of the senior partners have implemented in their previous careers., wa Establishing any subsidiary is a question of getting the balance right: to build responsibility for the subsidiary and expertise in the local market, but at the same time make the subsidiary feel part of the global organization.

What is your final message on the commitment of TranScrip Partners to Australia?

Dr. Sree Haran: We feel that Australia is sometimes undervalued and underestimated in the pharma industry. Already in the early days of my career, Australia had the best scientists and investigators in the world, on a par with those in the US or Europe, but there were perceived issues that it was a very difficult environment in terms of regulatory hurdles and rapid enrolment into clinical trials. Maybe in the 1980s and 90s that was the case, but the regulatory environment has definitely changed and the commitment of the government to grow the biotech sector and the emergence of Australia as an Asia Pacific Hub augers well for the future..

Dr. Morris-Smith: Australia has always been seen to be key within Asia-Pacific region and as the regional clinical trial activity grows, there is still a respect for the gold standard quality that Australia offers the research world. The cultural links with Asia are here already within the country itself and for many years it has been seen as a gateway to Asia. Some companies have recently relocated there hubs into Asia where there is a high volume of clinical trial work. With Australias strategic and

innovative background, and our foucs on drug development rather than clinical trials, TranScrip hopes to look at regional strategies and how Australia can truly integrate itself in the Asia-Pacific region and significantly contribute to the global market and to help this region be truly deserving of the value it really offers drug development. That is what excites us.

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