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The general manager of one of the leading CROs in Romania explains how the country in gathering pace as a top tier clinical trials destination country within the region and how the priority is now about on-time project delivery.

Could you please start by introducing PSI and its engagement with the local market?

PSI is known in the industry as a global CRO that delivers clinical trials on time and on budget. I find it remarkable that PSI has such a clear, straightforward differentiator.

The company was established in Switzerland 20 years ago and is, to this day, fully owned its operational management with no outside investment. This too is pretty unique for a 1,500-staff global CRO operating in 50 countries.

We started our Romanian office in Bucharest in 2002. The office has over 100 employees and is known for its really low staff turn-over and stability.

PSI runs clinical trials in a variety of therapeutic areas. Oncology, infectious diseases and CNS are our most prominent areas. Here in Romania, we are proud to say that we have been acting as an â??antibiotic powerhouseâ?• (quoting one of our customers) over the past several years. Weâ??ve engaged in many major antibiotic trials (CABP, cUTI, abdominal infections, skin infections, bacteremia) that produce pivotal data for the FDA and EMEA approval.

The bulk of our in-country work is in phase II and phase III and PSI-Romania often noted for our achievements in enrollment and data quality. Drug development is always a race against time and we continuously educate our investigators about the importance of meeting enrollment targets.

In an era of clinical trial globalization, how does Romania rank as a destination country?

Statistically speaking there are now around 4000 new chemical entities in development across the world and a full 60 percent of those trials are conducted exclusively in North America and Western Europe. The US alone hosts some 40 percent of total daytime clinical trials. However, there is no doubt that alternative regions are becoming increasingly attractive as destination venues. Romania is certainly one of those countries experiencing remarkably rapid growth in the clinical trials domain.

The total number of ongoing trials this year in Romania is 1714 compared to 4054 in Poland which can be considered the CEE leader with its comparatively larger population. More revealing, however, is the disparity in numbers of trials being conducted by neighboring countries with smaller populations: Hungary, which is on 2556, and the Czech Republic on 2818. These places have less than half the population, but are managing to perform getting on for double the trials. Itâ??s clear there is a significant gap to be bridged and that Romania still has a great deal of unrealized potential still to be fulfilled.

On the other hand, the statistics are much narrower for certain therapeutic areas. So far in 2015 there have been 176 trials conducted in Romania relating to infectious disease. This compares to 171 and 187 in Hungary and the Czech Republic respectively. When you take into account population size there is still obviously scope to do more, but the gap is not so large.

How strategically important is PSIâ??s Romanian office in comparison with the rest of the European offices?

We believe that every one of PSIâ??s offices, whether anywhere across Europe, Russia, USA, Latin America, South Africa or India, has a unique strategic opportunity to contribute to the global impact of the entire PSI. Our focus is not on competition between countries, but on their integration into a global tribe that is fully aware of how competitive the CRO industry is and has every intention to remain the CRO of choice for the old and new customers. This takes a village. We share, mentor, learn from other PSI office on daily basis.

Last year 6 staff members from PSI-Romania got nominated for the PSI Hero annual award based on their contribution to the PSI brand and reputation. Yes they are based in Romania, but they contributed on the global level and thatâ??s what counts at PSI.

What makes Romania so attractive then?

First and foremost is the availability of highly educated and trained professionals in newly established private and governmental research centers. This is complemented by a strong pace of investment aligned with a fair price allowing us to expedite the critical path to fast patient recruitment. All of this differentiates Romania from much of the rest of Europe. The fact that Romania adopted all the EU regulations well in advance of accession also gave the local clinical trials industry a head start.

On the flipside, sometimes the local requirements can be overly onerous. There are certain instances such as for Phase I trials where Romanians have to obtain special authorizations to perform them. In comparison, neighboring countries arenâ??t required to obtain special authorizations immediately giving them a competitive advantage. Moreover, there are thousands of clinical trials centers facing the requirement to obtain authorization every second year so trials lasting more than two years will need to be reviewed and this will cost time. Such delays impose an unnecessary additional burden on all stakeholders: CROs, investigators, site managers, sponsors and so on. To reap the benefits of the region, one needs to have a very strong, diverse, multi-talented, highly-attuned regulatory team in place in Romania and I can proudly say that PSI does. Many years ago we also invested in state-of-the-art drug storage facilities that, in time, became a GMP certified facility.

PSI differentiates itself from its competitors in its commitment to â??on-time project deliveryâ??. This seems a bold move in a local market well known for its unpredictability. How do you ensure this level of project speediness?

It takes honesty and a lot of hard work. First, you need to do a really good feasibility in order to â??marryâ?• the sponsorâ??s dreams with the brutal realities of clinical research as far as standards of care, logistical requirements, regulatory complications, competitive studies, levels of sophistication of data collection tools, etc. You need to engage people that really understand how things are done in Romania and can provide realistic time estimates for every step of the start-up process. You need to see how what we can contribute fits in with the global study timelines and patient enrollment commitments. And then we need to deliver on our promise. Nothing fancy, just doing the good old hard thing (smiles).

If we succeed, we celebrate; if we fail, we own up. This is how I was brought up at PSI and how I want my team to function. I recall some trials with start-up delays in Romania. This means you need to double or triple your efforts with the sites to gain time in enrollment. We caught up nearly every time, because we expected it of ourselves. Otherwise, weâ??d be letting down our PSI teammates in other participating countries. And that we canâ??t afford. I am finding that our customers appreciate that spirit at PSI. Maybe thatâ??s why they tend to come back with new work or recommend us to friends.

And we like tools and gadgets to help us reach our goals. Smart technology platforms improve communication with sites and can earlier identify potential data problems. Here again, Romania potentially holds a competitive advantage because the nation is visibly more tech-savvy and wired up than the rest of the neighboring regions. At PSI, we invest in developing clinical trial systems that allow us to gain a real life perspective during the project lifecycle.

In April, CenterWatch ranked PSI as number one highest performing CRO globally as far as site relationships. How was such a feat achieved? And to what extent does this raise the bar for the Romanian office?

It was nice to get this nomination. I know that many PSI countries, as well as Romania heard many good things from investigators, when this award became public. The ability to generate solid, trusting, long-standing relationships with the sites becomes a differentiating feature that distinguishes successful CROs from the rest of the crowd.

In Romania, we have forged preferred partnerships with certain sites and investigators and do everything in our power to maintain them. Throughout the years weâ??ve enjoyed repeat business with different centers which afforded us an advantage in gaining new contracts in an increasingly crowded field where more than 50 percent of workload comes direct from referrals and repeat business.

As for the CenterWatch independent survey of principal investigators, sub-investigators and study coordinators that ranked us as number one CRO to work with, we must build on this achievement. We must bear in mind that staying in the top position is a far greater challenge than getting there in the first place. It is essential we guard ourselves against complacency and continue to fine-tune our way of doing business. We must continue to push the boundaries and further improve.

How challenging is the competition in Romania?

The Romanian market appears pretty crowded if you count up the number of active and present CROs. Closer inspection, however, demonstrates that this is an illusion. If you look at the figures I presented to you earlier, you will see that thereâ??s a huge amount of slack in the market and

unused potential. The cake is big enough for everyone. Thereâ??s a vast amount of potential work to be done. If you compare how many clinical research sites there are in Romania compared to its neighbors, or consider the number of patients out there eligible for participating in the studies, thereâ??s scope for doing a whole lot more.

The global trend is for pharmaceutical companies to subcontract and externalize clinical trials rather than attempting to do them in-house. This goes hand in hand with CROs taking on new responsibilities. Nowadays we have to rise to the mantle of being a one-stop-shop that understands a siteâ??s needs, the challenges they face and can act as an advisor and provider of solutions. We have been empowered far beyond the traditional task of the mechanics of clinical trial monitoring. The real challenge is to learn from history, embrace the future and adapt to evolving trends.

What is your final message to our international readers?

Eighteen months ago, my own father was diagnosed with polycytemia vera having suffered an ischemic stroke and the doctor treating him proposed an alternative treatment to the historic medication currently available on the local market. That alternative was to participate in a major phase III pivotal study where he would receive access to latest generation therapies provided he met the inclusion criteria of the trial in question. This is the sort of hope our work provides to patients. It brings home the sheer importance of our activities. In supporting the medical profession we can enable those in need to access the very latest therapies. This is what drives and motivates us every day. We know our hard work matters.

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