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The directors of one of the leading in country contract research organisations, explain exactly what makes Romania such an attractive destination for clinical trials. They also give some indications of how the already booming clinical research is expected to thrive, and how there will remain plenty of work for all.

Could you please start by introducing INC Research and its global offering?

INC is headquartered in Raleigh, North Carolina, United States. We maintain operations across six continents and have experience spanning more than 100 countries. We provide the full range of clinical development services from Phase I to Phase IV for the biopharmaceutical and medical device industries. We actually started off as an academic-driven research organization in the 1980s until the official establishment of INC Research in 1998. The acronym â??INCâ?• actually stands for â??Integrated Neurosciences Consortium.â?• From that point on, we continued to grow and expand our service offering for our customers and the patients we ultimately serve. In the very beginning we were focused primarily on CNS but, by virtue of a series of key acquisitions (including competitors such as MDS and Kendle), we have significant depth and breadth of expertise covering all the main therapeutic areas, including CNS, oncology, cardiovascular, metabolic, infectious diseases, etc.

Our global client base ranges from big pharma firms to small biotech entities while our project capabilities are also pretty comprehensive: our experience spans small-scale consulting projects through global clinical trials covering dozens of countries, enrolling thousands of patients, spanning numerous years and acting as a pivotal juncture for our clients in their quest to obtain approvals for new drugs.

How does this translate to the local level in Romania?

 INC Research sits firmly within the top-tier Contract Research Organizations

(CROs) in terms of geographic reach, number of personnel engaged in projects and revenue stream. Recently we were ranked â??Top CRO to work withâ?• among large global CROs in the 2015 CenterWatch Global Investigative Site Relationship survey. INC Research is the only CRO to rank consistently among the top three CROs in all CenterWatch relationship surveys conducted with investigative sites across the globe since 2007. Our aim is to replicate these successes on the ground in Romania.

Our focus is on establishing INC in Romania as one of the more heavyweight players in the region. We are very much positioning ourselves as the connection point among the three main stakeholders in the clinical research sphere: our customers that are the pharmaceutical and biotech firms developing new drugs and innovative health technologies, the investigative sites, and the patients for the benefit of whom we work to bring to market cutting-edge therapies to market. Thatâ??s our crucial mission that motivates us each day. In Romania to date, weâ??ve mainly conducted Phase II and III trials with a firm focus on oncology, CNS, , cardiovascular, metabolic, rheumatology, infectious diseases, etc.

Locally, we make a special effort to reach out not only to university hospitals with their medical talent pools, but also small healthcare practices in some of the more remote regions. Our rationale is to try to penetrate the nationâ??s healthcare structures, including both the private and state sector spheres with an inflow of research, new thinking and investment. That way we can be a driver of improved health outcomes and sustained development.

What distinguishes you from the competition in what is an increasingly crowded field in Romania?

One of the hallmarks of INC Research and a key differentiating for our Company is our therapeutically aligned teams, which is our strategy of grouping specialized experts around specific therapeutic areas. Clients and patients both like to have subject matter experts for the specific trial being conducted rather than medical generalists. This means that our CNS trials, for instance, are conducted at each level by personnel who have dedicated their careers to that particular therapeutic field. That way, the pharma client, the patient and the site management can all have total trust and confidence in our recommendations and methodologies.

At the end of the day, there are three main pillars of a successful clinical study: a scientifically valid and internationally feasible protocol; motivated investigators who are qualified and appropriate for a particular study; and investigators that have eligible, informed and consented patients to participate in the study. Then on top of that, we go the extra mile by selecting CRAs that have the experience and passion to monitor in a particular indication when most of the CRO industry remains functionally aligned and allocates staff based on availability and proximity rather than therapeutic expertise. By contrast, our study teams are capable of performing not just the traditional auditing, monitoring and other operational tasks, but also of responding to the scientifically specific issues sites encounter.

We deploy our own unique methodologies such as the â??INC pressure testâ?• whereby multi-disciplined teams get together to review a clientâ??s drug development strategies from each of their operational, therapeutic and clinical perspectives. We also always strive to offer a customized

solution, as opposed to a readymade, one-size-fits-all shelf approach that tends to be the mainstay of many of our competitors. Instead we listen intently to our clients to determine their unique needs and expectations and then present them with carefully adapted, but streamlined processes that are reliable and proven to deliver.

With respect to our clinical research sites, we strive to build special relationships based on long-term collaboration, commitment and trust. This is because we recognize the real value and insights sites can bring in terms of patient enrollment and diligent work. Considering a site as a mere supplier of a service on a transactional basis is to underplay their importance. Instead the relationship more is akin to a client account or asset. We are there for them around the clock as facilitators, enablers and partners, with continued dedication to providing them with optimal support for their work.

In an era of clinical trials globalization, just how appealing is the Romanian market?

From a geopolitical perspective, Romania has the second largest population in Central and Eastern Europe (CEE) and is part of the EU club of nations. Large market size equates to lots of patients so that is definitely a plus factor. The healthcare system is also decent and operationally functioning so we can identify good research sites and investigators for our activities. The quality of the talent pool is frankly excellent: they possess a solid medical knowledge, high standards of English language and are keen on connecting with international medical networks and communities. The costs of monitoring, enrolling and conducting studies are also significantly smaller than in other countries.

Romania has the same regulations as all EU countries, which means weâ??re aligned to the United States and Europe. Whatâ??s more, this is not especially new for us. For the clinical research domain, accession wasnâ??t a shock or game-changer. The transition was actually very smooth because weâ??d had up-to-date clinical trial regulations and quality processes for data collection well ingrained many years previously. As a local industry, weâ??ve had many clientsâ?? audits and competent authorities inspections (including FDA and EMA) with good results. Ironically, the quality of data from clinical trials in Romania can be considered superior to data collected in many Western European states if you quantify, for instance, the number of observations resulting from audits or the number of queries generated by data collected at Romanian sites. Enrollment is also much better. We can enroll eligible patients faster and in higher numbers than for the equivalent study in North America or Western European countries. The same goes for the speed of time taken to execute contracts and set up sites. .

Nor should we forget about Romaniaâ??s very distinct epidemiological profile and the value additions that can bring. We have the largest population of patients infected with hepatitis C in CEE: approximately 1 million out of 20 which is a full 5 percent compared to Western European countries where it is more like 0.25-0.5 percent. This is very much a legacy from the communist era when basic healthcare sanitization procedures tended to be overlooked: transfusions were conducted using infected blood banks, invasive operations like dentistry were performed without rigorously sterilized equipment and sharing of needles was commonplace. The patient cohort for HIV/AIDS is also very distinct and constitutes the largest pediatric population in Europe. A high prevalence of antibiotic resistant bacterial strains represents a further peculiarity. As a result, Romania suddenly becomes the obvious destination for trials geared toward research in each of these areas.

Nevertheless Romania would seem to be facing stiff competition from some of its neighbors as a clinical trials destination countryâ?¦

Itâ??s an objective fact drawn from the index of EU clinical trial penetration that penetration is four times less in Romania than in the Baltics, Czech Republic and Hungary and roughly 2 time less than Poland. This means there is still much room left for improvement. Whatâ??s perhaps holding

Romania from realizing its full potential is the fact that the country, along with Bulgaria, is perceived as lagging behind in terms of infrastructure.

Because of these, often misinformed, perceptions, sponsors could be inclined to hold off their investments or look elsewhere. The reality on the ground is very different, however. Support infrastructure, both hard and soft, for holding the trials is excellent and newcomers are often highly impressed. Our task is to encourage the sponsors to come out here and try Romania out. Those that do are almost certain to return. The first step is the most difficult, but repeat referrals keep on flowing. Our message to the sponsors is that Romania is worth going for.

How supportive are the authorities and associated regulatory landscape when it comes to shortening time horizons for approval and review of submissions?

The regulatory apparatus is broadly supportive. Efficacy and safety of new drugs is, of course, one of the main missions of the NAAMD and this is rightly so. Being supportive of the industry per se is only a second order priority especially when they have finite staffing capabilities. That said, we are collaborating with the authorities at the association-level to help them streamline and optimize their own processes with a view to obtaining faster approval and review of submissions.

The approval mechanism is more challenging for Phase I and, as a result, there are fewer Phase I trials conducted in Romania. There arenâ??t many facilities with the certificates to legally conduct them, which again impacts the volume of Phase I trials rolled out. For big hospitals, obtaining the authorization for conducting clinical trials is more or less a formality (albeit a rather bureaucratic one). For smaller medical practices, this can be burdensome in terms of costs and time so that is yet another area where we are striving to work alongside the authorities to identify new operating procedures where every stakeholder is a winner.

Within INC Research, we have implemented the â??Trusted ProcessÂ®â?• and enhanced it with a view to improving predictability and diminishing trial timelines through more efficient delivery.. INCâ??s median study startup time of 120 days is almost four weeks faster than the industry median. Our median database lock time of 51 days is four days faster than the industry median. Running a clinical trial is a very complex endeavor with many parallel activities revolving around a critical pathway. By breaking down and analyzing and optimizing each activity, we have managed to realize these new efficiency gains.

What benefits does clinical research bring to the chronically underfinanced Romanian healthcare system?

This is a massive opportunity for not only importing knowledge and know-how, but also for drawing in equipment, investment and novel medications. This offers hope to entire categories of patients that couldnâ??t be covered elsewhere by the local healthcare system and would otherwise risk being left behind. Clinical research also provides an opportunity for Romanian doctors to get updated on the latest scientific advancements, to stay informed and to maintain contact with key option leaders from other countries. After a specific trial ends, relationships are often maintained and cross-pollination of ideas continues to take place. This means there is a whole informal knowledge transfer at play, which brings modernity to the Romanian healthcare system. This is a process that should not be overlooked, because the end impact is great.

Nor should we overlook the fact that our trials introduce an attention to detail and rigorous practice. Clinical trials represent one of the most regulated domains in the world. They can therefore be seen as a school for transmitting best practice and for raising the game of our entire national medical system.

What is the outlook for the Romanian clinical research segment for the next 4-5 years?

Outsourcing clinical research functions is a growing industry worldwide. Globally thereâ??s been a surefire shift in expertise away from the pharmaceutical industry with regard to clinical development. It is increasingly accepted that the task of bringing new therapies to market is best handled by specialists well-versed in guiding new products through the investigative process.

This emerging trend can be explained by a several factors. Firstly, global reach has become tremendously important in the sense of gaining access to the right, genetically diverse patient groups and experienced clinicians. This capability is something that even the largest pharma companies donâ??t possess within their in-house product development divisions. Nor do they hold a level of exposure to new compounds, studies and products equivalent to an experienced, fully-fledged CRO like INC Research. Finally, global organizations like INC with devolved in-country offices staffed by local experts can offer a much more in-depth understanding of the regulatory landscape and the local knowledge for proper liaison with the competent authorities in a specific country.

The Romanian market can be seen as a local expression of these global trends. Romania fits into these worldwide networks and, with a market size and patient profile of that magnitude, becomes a fundamental link in the chain. The local market is growing, the untapped potential remains deep and there is plenty of work to do. A rise in tide floats all boats so to speak. We usher in the future with open arms.

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