Julia B. Kondakov, director of business development, Accell Clinical Research, explains why Russia is a gateway to strong patient recruitment for oncology trials

Oncology clinical trials are complex, and particularly challenging in terms of patient recruitment. The choice of countries for multicenter, multinational oncology clinical trials depends on a multitude of factors, including the regulatory landscape, availability of comparator drugs, epidemiology of the disease, the available standards of care, the complexity of a clinical trial, requirements for specialised imaging technologies and last, but not least, the future marketing plan. According to ASCO, only about 3% of oncology patients in the United States choose to participate in a clinical trial (1), leading to slow recruitment and forcing drug companies to look to underutilised countries for improving patient recruitment and retention.

Predicted to rise from 11th to 8th place in the global pharmaceutical rankings (5), Russia remains a promising country for oncology clinical studies. Of the total number of clinical studies granted approval by the Ministry of Health in 2014, only 18% or 84 clinical studies were in oncology (2), leaving substantial room to perform more oncology clinical trials with experienced investigators at well-equipped sites. The regulatory climate for clinical studies has warmed up since the implementation of new legislation in 2015, and the timeline for receiving the agency's decision on a clinical trial application is only 40 business days.

The real benefit of working in Russia, however, lies within the established and well-defined multi-tier oncology care network, that inevitably captures the majority of oncology patients nationwide. Primary care physicians typically refer patients to the first tier of the oncology network, which includes specialised oncology offices at hospitals and ambulatory clinics. There, regional oncologists perform diagnostic procedures, treat patients of certain groups, or prepare them for further specialised care. The number of these offices has reached 4,758 in 2014. The second tier comprises a nationwide network of 100 specialised oncological early treatment and prevention centers, totaling 27,349 beds (4). These centers serve a large population from a defined region and specialise in detection and treatment of malignancies. The top tier of the system is occupied by large oncology institutions of national significance, which oversee the work of the oncology treatment network, develop guidelines, and offer patients high-tech diagnostic methods and high standards of medical care.

The Russian government spent approximately 1.3 billion US Dollars (47 billion Rubles) on the National Oncology Program initiated by the Ministry of Health in 2009 to support the modernisation of the oncology care network. The program completed in 2014, leaving in its wake 101 new oncology facilities. Over 4,000 existing oncology facilities received more than 389,000 units of modern equipment, including over 700 MRI and CT scanners and over 6,500 units of X-Ray and angiography equipment (6). This means that potential clinical sites in Russia can meet specialised imaging requirements and have an excellent technical base for accommodating oncology clinical trials.

Russia registered 566,970 new oncology cases in 2014, a 5.8% increase from 2013. The total number of oncology patients in Russia by the end of 2014 reached 3,291,035, or 2.25% of the population. The prevalence of all malignancies grew in 2014 by 38.8% from 2004, and reached 2,257 per 100,000 population (4). But the availability of private healthcare options in oncology remains limited. Oncology treatment and care are funded from a financially restrictive and limited federal Compulsory Medical Insurance fund, resulting in the increased interest of both patients and investigators to participate in clinical trials, and positively affecting patient retention.

The reality of oncology trials in Russia supports the claim of high patient recruitment. For example, consider two recent oncology clinical studies performed by Accell Clinical Research. In a Phase II head and neck cancer study, Russian sites achieved recruitment rates six times higher than in Western Europe, and 7.5 times higher than in the US, and, in a Phase III clinical study in the same indication, 8.8 times higher than in North America.

Though the typical caveats cited about working in Russia include regulatory challenges, unclear and lengthy customs procedures, drug shipment control and language barriers, with the right clinical development partner and diligent planning, these perceived challenges could be overshadowed by the immense advantages offered by the fast patient recruitment and exceptional work quality. Often, the right partner can be a local CRO with substantial experience in their market and established connections with the key opinion leaders and well-equipped large hospitals. It is important for oncology drug companies to be able to leverage such local expertise and to assess the suitability of the country at an early planning stage.

Selecting the right regions for strong patient recruitment in an oncology clinical trial can be an intimidating task, but rather than overlooking an excellent opportunity to tap into a large oncology patient population and take advantage of the experienced investigators and well-equipped sites, companies should rigorously assess the country options for a right fit. With comprehensive and objective evaluation criteria, and the right CRO partner with expert local knowledge, drug developers are likely to be able to realise the potential benefits of patient recruitment and cost saving benefits offered by Russia. **P**

References

(1) 2004 ASCO Annual Meeting Proceedings (Post-Meeting Edition), Journal of Clinical Oncology (July 15, 2004).
(2) Synergy Orange Paper 2014
(3) Zang Y, Lee JJ. Adaptive clinical trial designs in oncology. Chin Clin Oncol 2014;3(4):49. doi: 10.3978/j.issn.2304-3865.2014.06.04
(4) State of oncological help to the residents of Russia in 2014, Moscow scientific research center n.a. Gertzen – branch of Federal State Budgetary Establishment "National medical radiology research center" of the Ministry of Health of Russian Federation (Moscow, 2015)
(5) IMS Health
(6) Orange paper, Synergy Research Group, 2014