Clinical Research Trials Continue On In Ukraine

Maksym Iurkin, MD
Country Manager, Ukraine
Introduction
The political situation in Ukraine over the past year and a half has raised legitimate questions about whether or not clinical research trials can continue to run smoothly and continuously. An examination of the current map of Ukraine reveals a country largely intact, as the crisis has been confined to the region of Crimea, as well as the eastern cities of Donetsk and Luhansk. The business of conducting trials mirrors the political situation in Ukraine: in the vast majority of the country controlled by the central government, clinical studies remain completely viable and continue showing healthy dynamics.

The situation in Ukraine has become worldwide news since its genesis in December of 2013, so it would be understandable for stakeholders with business interests there to seek clarity. For the leadership of a contract research organization (CRO) observing these events with keen interest, the reaction must have certainly been twofold: first, the recognition of human tragedy; in addition, though, the capacity to gather information to ensure that the vital work of conducting clinical trials can continue. The data clearly indicates that the clinical trials industry in Ukraine remains stable and operational.

The Mechanics of Clinical Trials in Ukraine Remains Unchanged
Because of the imagery and accompanying stories in the media, it would be understandable to conclude that Ukraine is in general tumult, and that basic government and health services have been interrupted or compromised. But from the inside looking out, this simply is not the case in Ukraine. In most of the nation (other than the eastern areas in crisis) the mechanics of clinical trial approval and operation remain entirely intact. Additionally, new and ongoing clinical trials continue to recruit well and meet deliverables.

In July of 2012—or approximately a year and a half before the political crisis began—there were a set of marked changes put in place governing the application procedure of clinical trials. In short, the application became a two-part process, with both a national and a local component. The application and accompanying materials are reviewed by the State Expert Centre (SEC); then, if accepted, an approval letter is generated by the Ukrainian Ministry of Health (MOH). This part of the process takes approximately 60 days. In addition, a Local Ethics Committee (LEC) is required to be established and maintained at the clinical trial site. This group (which includes doctors and other professionals, often including a priest and a lawyer) meets periodically to make certain that ethical and legal issues are continually addressed. A trial typically takes nine to 12 weeks to be approved both by MOH and LECs, which is on par with other central European countries.

It is important to note that despite the upheaval in parts of the eastern part of the nation, the Ukrainian Competent Authority (and the Ministry of Health) continues normal operations. More importantly, clinical trials and their respective sites and local committees remain up and running. This reflects a healthy business environment in which to conduct studies, and should allow the leadership of CROs to remain confident in ongoing investments in Ukraine.

A Current Snapshot of Clinical Trials in Ukraine
The dynamics of conducting clinical research trials in Ukraine are unimpaired, as evidenced by the continuing number of trials approved by the Ukrainian Competent Authority

“...as evidenced by the continuing number of trials approved by the Ukrainian Competent Authority”

– Maksym Iurkin, MD

www.chiltern.com
In 2012, the total number of approved clinical trials was 265; strikingly, there were 269 in 2014. Therefore, the political crisis has had no measurable effect on the creation of new studies. In fact, more than 220 new clinical trial were approved since February of 2014 (the start of the events in Crimea and the two eastern areas of Ukraine); additionally, 98 new clinical trial applications have been approved within the first two quarters of 2015 (including 72 international in origin), which puts the country on pace for approximately 200 for the calendar year.

In mid-2015, there were 358 clinical trials being conducted in Ukraine, including 301 international in origin. And there is great diversity in indication, with pulmonology and oncology leading the way with 30 studies each, followed in descending order by psychiatry and neurology, rheumatology, endocrinology, cardiology, and hematology. The key takeaway is the fact that the essential work of executing medical research in Ukraine remains uninterrupted by the political events.

Challenges and Opportunities in Clinical Research in Ukraine

There are challenges to overcome in executing clinical trials in Ukraine. In the regions affected by the ongoing conflict, there have been no new clinical trials approved by Ukrainian Competent Authority. Although it has been established that the lack of study activity in these areas has not dramatically lessened the overall number of studies in the nation, this still represents untapped potential. There is great incentive in Ukraine to prove that its people remain able to run clinical trials and meet required targets, despite the unrest in two eastern regions. So far, that is exactly what has occurred, as they continue to approve trials, recruit patients, and conduct research.

References
