

CLINICAL TRIALS IN UKRAINE: CURRENT STATUS AND SHORT TERM OUTLOOK

For almost two decades Ukraine has been an attractive locale for clinical research, in large part due to its rapid patient recruitment and sound investigator expertise.

In the last several months the political situation in Ukraine has become rather volatile and remains the epicenter of international contention. Albeit, in this brief report we will forego both political and economic analyses, leaving it to the experts. The goal is to provide a brief status update on the ongoing clinical trials and give recommendations on how to mitigate both present and future risks.

As it stands today, Ukraine's Ministry of Health, not unlike the rest of state offices, has been under immense pressure. Despite that, regulatory approvals are in line with the historical timelines. As such, a dossier Cromos Pharma had submitted on October 30th, 2013 was approved on February 7th, 2014, and for the dossier submitted on January 14th we have received a request for additional information on February 7th. These processing times are encouragingly similar to what we saw in 2012-13.

Based on our internal and some limited external data, both screening and recruitment in the ongoing clinical trials have not been adversely affected either. Whether this is a residual effect of earlier pre-screening efforts is difficult to say at this time. In addition, we are unaware of any reports of irregular functioning of the in-hospital or ancillary services. Thus, based on the available data, it has been *business as usual* in the ongoing clinical trials across the country.

Considering the aforementioned state of affairs, we can say with relative confidence that the current clinical programs have high probability of proceeding with little or no interruptions. It still remains unclear whether the political situation will have any effect on patient enrollment. Nevertheless, we have been encouraged by how unscathed the clinical trial space in Ukraine has been to date and expect robust recruitment in the months to come. *Consequently, we recommend that all ongoing clinical trials be continued as scheduled.*

One issue of concern is that the economic constraints currently faced by the Ukrainian government will translate into shortages of certain high-priced hospital supplies, such as CT/MRI IV contrast, essential and non-essential medications, etc.

Thus, we advise that project management teams pay extra attention to the logistical aspects of trial conduct at each site, with possible *increase in frequency of monitoring visits and regular telephone communication with the investigators and trial coordinators.*

While our studies have not been directly affected, there have been seldom unconfirmed reports of logistical delays in IMP/CTM shipments due to interruptions at the customs. In order to effectively monitor the CTM/IMP logistics, we have established *the hotlines with the couriers and the depot vendors* and have requested bi-weekly updates on customs clearance and shipment deliveries.

With political controversy around Crimea and presidential elections scheduled for late May, we recommend that *all clinical trial startups be halted until the beginning of June.*

We remain cautiously optimistic that the worst of this regrettable crisis is over. Having said that, given the number of the remaining unknowns, we have taken preemptive steps to ensure safe working environment for our staff.

We will stay in constant communication with Ukrainian competent authorities, customs and courier agents and will keep you abreast of any new developments.