

Related Articles by Company

[Weekly CRO Report - 7 April 2014](#)

Related Articles by Topic

[Xeltis seeks CRO by 2H14 for Phase II study of implantable heart valve - CEO](#)

Ukraine's CRO industry could benefit from political standoff with Russia, especially if it leads to expedited EU membership - experts

SanaClis decides not to start any new studies in Crimea

Ukraine CRO business could benefit from potential EU membership or depreciating currency

The CRO industry in Ukraine could benefit from the country's current political uncertainties regarding Russia, especially if they lead to expedited EU membership, said experts interviewed at the DIA EuroMeeting in Vienna last week.

However, the situation could pose more difficulties for Crimea as some clinical trial sites stop initiating new studies in the region, they said. Though it is impossible to predict how the situation will develop over the next six months, businesses will find ways to run trials in both territories, said a regulatory source and several other experts.

The situation

Russia annexed Ukraine's Crimea peninsula last month. During a 1 April 2014 meeting, the North Atlantic Treaty Organization (NATO) suspended all practical cooperation with Russia. NATO also discussed whether Russian President Vladimir Putin is likely to launch a new invasion on Ukraine with troops currently situated on eastern Ukrainian borders.

With the EU on hiatus as to what action to take against Russia, CROs and sponsors should consider how the situation could impact clinical work, said Morell David, principal consultant, NDA Group. In both regions, there are signs some sponsors have become cautious about starting trials, especially US-based sponsors, said Alexander Fetkovsky, partner, logistics manager of Slovakian CRO SanaClis.

SanaClis runs trials in Ukraine and Crimea, though after risk assessment it has decided it will not start any new trials in Crimea at this time, said Roman Hrynychuk, clinical operations manager, business development. Ongoing Crimean trials will continue to run under normal conditions and SanaClis will continue to provide shipments to sites in the area, added Fetkovsky. However, SanaClis will not initiate new Crimean sites for those studies, Hrynychuk added.

The pair did not state exact reasons from the risk assessment behind the decision, though Hrynychuk did note Ukrainian banks are likely to close their offices in Crimea. SanaClis has offices in Russia, so it could continue to run trials for Crimea through those bases, Fetkovsky added.

In Ukraine, on the other hand, clinical trials appear to be running as normal, despite Russian soldiers being on the eastern border, David said. The European Business Association recently asked for feedback from pharmaceutical players working in Ukraine and found no impact to patient safety, Hrynychuk said. Trials are running as normal, even in eastern Ukraine, he added.

Running clinical trials in Ukraine could become even more attractive to European sponsors as the current situation could accelerate the country's entry into the EU, providing an increased alliance with sponsors, David and the regulatory source noted.

Discussions about Ukraine becoming a member state have been ongoing for some time, but there will likely be more urgency to grant entry after Russia's recent actions, David said. The European Commission is also beginning to realise Ukraine's focus on clinical research, he noted.

The economic benefits for Ukraine joining the EU could also drive industry, he said, citing swelled industries in Latvia and the Czech Republic since they became member states and received EU economic support.

On the other hand, the depreciating local currency -- the hryvnia (UAH) -- against the euro is an advantage for Ukraine, in terms of attracting European sponsors as trials cost less due to the currency rate, Fetkovsky noted. One month ago, EUR 1 was UAH 11, and now it is around UAH 14, Fetkovsky said, noting Russia is facing a similar situation.

Regulatory authorities and investigators are now more motivated to drive the clinical trial sector because there are less sponsors heading to Ukraine than before the political issues arose, Hrynychuk noted.

EU member state requirements

However, becoming an EU member state takes time and preparation, including translation of the legislation into local language, the regulatory source noted.

In July 2013, Croatia became an EU member state, though the translation of EU legislation into Croatian first started in 2003 and took a full 10 years before it was accepted, said Viola Macolic Sarinic, head of Agency for Medicinal Products and Medical Devices (HALMED), Croatia.

The translation of the EU clinical trial legislation (directive 2001/83/EC) took around one-and-a-half years, she added.

Croatia ensured a quick implementation of clinical trial laws through an agreement with the EMA under which it gained access to assessments conducted by European agencies, Sarinic noted. HALMED used the documents to bring local legislation in line with EU law, she said. Croatia also worked with the Spanish regulatory authority to gain a real life understanding of EU legislation, she added.

Sarinic said she was unaware how advanced any negotiations for Ukraine to join the EU are, but noted she had previously been in contact with regulators over Pharmacovigilance. Ukraine seemed keen to implement EU Pharmacovigilance guidance

Company

[Aris Global, LLC](#)

[Nda](#)

[SanaClis](#)

Topic

[CRO Invitation](#)

[Medical Devices](#)

[Other](#)

[Other](#)

[Other](#)

[Regulatory](#)

Sub-sectors

[Drug supply](#)

Country

[USA](#)

Key Opinion Leaders

[Ambrish Mathur](#)

Intelligence Grade

Confirmed

[Email Analyst](#)

locally, she added.

However, becoming part of the EU may not make a big difference to business in Ukraine, as CROs have always been free to operate in the region, said Ambrish Mathur, vice president, strategic development, Aris Global. CROs established there will likely continue business as usual regardless of EU membership status, he noted.

by Natalie Morrison in London

About [Natalie Morrison](#)

Email the journalist team at editorialfeedback@biopharminsight.com