ACTO
ASSOCIATION OF CLINICAL TRIALS ORGANIZATIONS

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ACTO's Position

Organization and Conduct of Clinical Trials under the Conditions of a Pandemic

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Today, as the new coronavirus infection continues to spread worldwide, regulatory authorities in many countries, including the Russian Federation, have issued recommendations for conducting clinical trials under the pandemic conditions.

The Association of Clinical Trials Organizations has also found it necessary to formulate its own vision of appropriate steps by the industry in response to the current challenges.

The emergency measures taken today by the authorities to control the infection directly affect everyone involved in clinical trials. The requirement to self-isolate and the need to work remotely, the restrictions on citizens' movement and the limited access to medical institutions — these and other measures in different regions have already called into question the scheduled visits of patients to clinical sites, on-site monitoring and continuing compliance with the trial protocols and sponsors' SOP. Obviously, before the situation settles down, many deviations from the protocol will occur. It is also clear that today our highest priority should be the safety of all process participants: the patients, the hospital staff and the company employees.

In this regard, we believe that it would be wise for sponsors and contract research organizations to take the following measures:

1) If your company has managed to develop an operational policy for the pandemic period (a kind of "wartime SOP"), send it to the Ministry of Health, thus notifying the regulator of the temporary change in practice.
2) Whenever possible, replace field monitoring with remote monitoring (via telephone, video calls, etc.) or centralized monitoring.
3) If possible, arrange delivery of medicines to patients' homes directly from the local depot or from a medical center.
4) If possible, arrange at-home biological sample collection from your patients and provide for the samples to be collected by a delivery service from the patient's home.
5) If possible, arrange at-home patient examination with field visits or telemedicine.
6) Carefully document all deviations from the protocol and be prepared to present them upon request of the regulatory authorities.
7) Pay attention to the psychological support of the team.
8) Be flexible and take any other measures that seem reasonable in such circumstances, given the balance of benefits and risks for your trial subjects.