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ACTO's Position on Conducting Clinical Trials in Russia

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Taking into account the significant risks and the high degree of uncertainty in relation to conducting clinical trials in the territory of Russia, ACTO calls to focus on the principles of the Helsinki Declaration and the ICH GCP standards, and therefore, first of all, take care of the health, welfare and observance of the rights of patients.

In particular, ACTO recommends the following:

- postpone launching new projects, opening new sites, enrolling patients in trials which are already underway until the situation has been clarified, if the risks for trial subjects and the organization of the trial processes are high, and also if it is yet impossible to realistically assess the risks;
- consider it acceptable to approve amendments to the protocol concerning patient safety already after taking specific measures to ensure patient safety;
- continue recording all deviations from the protocol, thoroughly and in accordance with the procedure;
- if possible, try switching to working with available laboratories (local or based in countries where biological materials can be delivered), and also, whenever feasible, postpone the collection of biological materials until the logistical issues have been clarified;
- if possible, try to arrange new routes for shipping medicinal products, laboratory kits, other supplies and equipment for trials, during the use of which the transportation requirements can be ensured;
- consider delivery of the investigational product to the patient by a distributor engaged by the sponsor, whenever feasible, and if there are detailed instructions prepared by the sponsor and provided to the patient;
- premeditate alternative communication channels between the trial organizers, the research team and patients in case of problems in the operation of the existing channels.