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| **MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION** (MINZDRAV OF RUSSIA) | Ministry of Health of the Russian Federation(Barcode)Вр-1457989 |
| **MINISTER** | To subjects of circulation of medicinal products |
| 3/25, Rakhmanovsky per., bldg. 1, 2, 3, 4, Moscow, GSP-4, 127994, Tel.: (495) 628-44-53, fax: (495) 628-50-58 27 March 2020 No. 20-1/И/2-3651Your Ref. No. dated  |
| On issues concerning carrying out clinical trials of medicinal products in the midst of coronavirus COVID-19 pandemic. |  |

In connection with the World Health Organization declaring the outbreak of a new type of coronavirus COVID-19 a pandemic, the introduction of high-alert status in the Russian Federation and taking into account the current situation in the constituent entities of the Russian Federation, the Ministry of Health of the Russian Federation takes all possible measures aimed to contain the spread of coronavirus infection, also aimed at reduction of social contacts frequency that can contribute to the virus spread.

The conditions of a tense epidemic situation and the restrictions imposed by the high-alert mode may affect the processes of conducting clinical trials of medicinal products, lead to difficulties in fulfilling the procedures of the protocol of clinical trials regarding provision of clinical trials participants with investigational medicinal products or observing the schedule of visits and laboratory / diagnostic examinations, established by the protocol.

In this regard, the organizers of clinical trials of medicinal products in cooperation with researchers and local ethics committees may amend standard operating procedures in the interests of participants in clinical trials with due regard to guarantee of reliability of the processed data. Any amendments should be based on a risk assessment of each individual ongoing trial.

The Russian Ministry of Health stresses that ensuring the safety of clinical trial participants is a priority.

It is of utmost importance that clinical trial participants are constantly informed of changes in visit and monitoring schedules.

In order to ensure the safety of clinical trial participants in the Russian Federation, adherence to good clinical practice (GCP) and to minimize risks to the integrity of clinical trials in the current epidemic situation, the Ministry of Health of Russian Federation considers it appropriate to recommend that clinical trial organizers focus their efforts on the following aspects:

* to consider the possibility of using the alternative methods for monitoring clinical trial patients (e.g., telephone contact, virtual visit, alternative location for assessment, including local laboratories or imaging centers), provided that this does not increase the risks for the trials participants and does not lead to the infringement of their rights and legal interests;
* to expand the possibilities of interaction with patients at home (for example, to organize the home delivery of drugs to the trials participants by employees of medical centers, to organize the collection of biological samples at the place of residence), provided that the trial organizer is able to ensure the proper level of quality of this process (i.e. compliance with the standards of the drug accountability, ensuring the proper quality of the samples, etc.);
* to take measures to minimize the impact on the integrity of a clinical trial, to prevent protocol deviations, unless they are aimed at eliminating the direct threat to the subjects of the trial or when the changes concern only the administrative and logistical aspects of the trial, and also to pay special attention to documenting each fact and the reasons for such a deviation;
* to take measures aimed at providing the maximum possible protection for the personnel involved in the clinical trial.

Given the importance of maintaining high standards for conducting clinical trials and complying with the laws of the Russian Federation governing the conduct of clinical trials of medicinal products for medical use, the Ministry of Health of Russia stresses that for the organizers of clinical trials and for supervising authorities, priorities are the provision of the patient safety and maintaining a reasonable benefit/risk ratio for subjects of the trial. Clinical trials organizers may also turn to other measures if, in specific circumstances, their adoption would serve the interests of clinical trial patients.

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