Precautions to Be Taken in Clinical Trials Due to COVID-19

Due to COVID-19 pandemic, precautions needed to be taken in the field of clinical trials where it is requisite to ensure the protection of the rights, safety and wellbeing of trial participants.

In this regard, European Medicines Agency published Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) Pandemic on 20 March 2020 and released revised Version 2 on 27 March 2020 and recently updated Version 3 ("EMA Guidance") on 30 April 2020.

The EMA Guidance encourages Member States to implement its rules to the maximum possible extent to mitigate and slow down the disruption of clinical research in Europe during the public health crisis. At the same time, sponsors and investigators need to take into account that national legislation and derogations cannot be superseded. Actions should be proportionate and based on benefit-risk considerations, on contingency provisions taken nationally and locally by the authorities, with priority given to the impact on the health and safety of the trial participant. Where a trial participant is unable to attend the site, other measures, such as home nursing, if possible given social distancing needs, or contact via phone or telemedicine, may be required to identify adverse events and ensure continuous medical care and oversight. However, the limitations and risks of such methods and the requirements for data protection should be taken into account and such alternative arrangements need to be adequately documented. It is noted in the EMA Guidance that the simplification measures proposed shall only last during the current public health crisis.

Even though Turkey is not a member state, the Turkish Medicines and Medical Devices Agency published an announcement regarding precautions to be taken in clinical trials due to the COVID-19 pandemic in Turkey on 20 March 2020.

In line with the EMA Guidance, the announcement states that sponsors of clinical trials should continuously assess risk and update their research organizations accordingly. This risk assessment should take into account the COVID-19-related priorities, reduce the burden of research centers and follow social isolation rules. The first issue to be considered at this stage is the safety of the clinical trial subjects.

The announcement discusses taking measures in relation to clinical trials, such as:

- Suspending or terminating early, when necessary, and informing the ethics committee of these situations.
- Determining the person responsible for implementing the emergency safety measures.
- Reporting protocol violations that arise as a result of COVID-19 to the ethical committee.
- Actions required to keep stock of the product higher than normal in case of possible customs barriers or quarantines.
- Limiting clinical trial center visits.

In addition, there is no need to submit physical documents to the Agency for the purposes of any clinical trial-related application. Documents can be filed electronically.

The measures explained in the announcement will be reviewed and updated by the Agency based on the evolving situation, and will remain valid until declared otherwise by the Agency.