

## **COVID-19: Precautions to be taken in clinical trials**

*Dicle Doğan and Fatma Sevde Tan, Gun + Partners*

On 20 March 2020, the Turkish Medicines and Medical Devices Agency published an [announcement](#) (Turkish language) on precautions to be taken in clinical trials due to the COVID-19 pandemic.

The announcement states that sponsors of clinical trials should continuously assess risk and update their research organisations accordingly. This risk assessment should take into account the COVID-19-related priorities, reduce the burden of research centres 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 centre visits.
- Conducting ethics committee meetings.

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 guidance provided 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.