Handbook on the EMA and OGYÉI Guidances on Clinical Trials during the COVID-19 pandemic

KPMG Legal Tóásó Law Firm

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Guidance of the European Medicines Agency (EMA)

The purpose of the **EMA** Guidance on Clinical Trials during the COVID-19 pandemic, issued on March 20, 2020, is to establish **general, EU-level** recommendations to those who participate in clinical trials. However, it also aims to **draw companies' attention** to the need to **comply with any specific national legislation and guidance** that may take priority over these recommendations.

Main recommendations to follow in connection with the ongoing trials:

- Conversion of physical visits into **phone or video visits**
- A temporary halt of the trial at **some or all** trial sites
- **Suspension or slowing down** of recruitment of new trial participants
- **Extension** of the duration of the trial and/or **postponement** of certain trials

Furthermore, according to the Guidance, in the case of ongoing clinical trials **on treatments for COVID-19**, it may be necessary to develop **alternative procedures** to obtain **informed consent**, as it is likely that the physical consent cannot be acquired.
In addition, it is necessary to consider the commencement or continuation of activities if the participants are at **any potential risk of COVID-19**.

Guidance of the National Institute of Pharmacy and Nutrition (OGYÉI)

On the basis of **OGYÉI**'s latest Guidance on the continuity of clinical trials, dated March 24, 2020, a **thorough risk assessment** of ongoing trials **shall be conducted**. Furthermore, **measures to improve patient safety and validity of data shall be imposed.**

According to the OGYÉI Guidance, it should be considered to **stop the patient enrollment process** during this period. OGYÉI also draws attention to the fact that the **use of electronic means for obtaining informed consent** and **providing patient information (package leaflet)** is **not permitted** in accordance with the provisions of the relevant legislation, even in the current state of danger.

Authorisation

- It is sufficient to send requests for clinical trials and substantial amendments using OGYÉI's online portal.
- Substantial amendment of the clinical trial, to ensure the continued involvement of the participant, can be issued as an "urgent safety measure".

Visits

- Conversion of physical visits into phone visits must be taken into consideration.
- In case it is not feasible for a trial site to continue the trial, it shall be suspended.

Monitoring

- Alternative proportionate mechanisms of oversight shall be preferred to reduce on-site monitoring.
- Providing the representative of the Sponsor with copies of medical records or remote control to electronic medical records is not allowed.

Distribution of IMP

- Re-distribution of Investigational Medicinal Products between sites, providing patients with supply for longer periods than originally planned during on-site visits, or delivery of the IMP directly to the patient's home may arise.

Should you have any questions, feel free to contact us.

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