REPUBLIC OF CYPRUS

PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH

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Guidance to sponsors on how to manage clinical trials during the COVID-19 pandemic

The European Commission, the European Medicines Agency (EMA) and national Head of Medicines Agencies (HMA) have published new recommendations for sponsors on how to manage the conduct of clinical trials in the context of the coronavirus disease (COVID-19) pandemic. The impact of the pandemic on European health systems and more broadly on society, will make it necessary for sponsors to adjust how they manage clinical trials and the people who participate in these trials.

The guidance provides concrete information on changes and protocol deviations which may be needed in the conduct of clinical trials to deal with extraordinary situations, e.g. if trial participants need to be in self-isolation or quarantine, access to public places (including hospitals) is limited due to the risk of spreading infections, and healthcare professionals are being reallocated.

This guidance includes a harmonised set of recommendations, to ensure the utmost safety of trial participants across the European Union while preserving the quality of the data generated by the trials. It also advises how these changes should be communicated to authorities.

There is specific advice on the initiation of new clinical trials for treatments of COVID-19, and in particular on the need for large, multinational trial protocols. This is in line with the call issued on Thursday by EMA's human medicines committee (CHMP) for robust trial methodology in clinical trials for potential COVID-19 treatments or vaccines.

The guidance was agreed by the Clinical Trials Expert Group (CTEG) of the European Commission supported by EMA, the Clinical Trials Facilitation and Coordination Group (CTFG) of HMA and the GCP Inspectors' Working Group. It provides a harmonised approach in the conduct of trials, in order to mitigate the negative effects of the pandemic.

In the EU, clinical trials are authorised and supervised at national level. Sponsors are advised to also check whether there might be specific national legislation and guidance in place to complement or in some cases to take priority over this new guidance.

Notes

1. The guidance on the management of clinical trials during COVID-19 is published on the European Commission's website.

2. For more information on the EU's response on coronavirus 2019-nCoV, see European Commission: Coronavirus response.

3. More information about EMA's response to COVID-19 is available here.

4. More information about the CTFG is available here.

5. Information on the GCP Inspector's working group is available here.

6. Information on the CTEG (Clinical Trials Expert Group) is available here.

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