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Press release

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Advice to sponsors on managing the impact of the war in Ukraine on clinical trials

In view of the disruptions caused by the Russian invasion of Ukraine, the European Commission (EC), the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) are issuing initial advice for sponsors on how to manage the conduct of clinical trials in this situation.

The ongoing war in Ukraine may require sponsors to adjust the way clinical trials are run in this region, and sponsors may need advice on how to deal with the impact of protocol deviations and other consequences of the disruptions. Certain changes and protocol deviations in the current situation are unavoidable, when for example scheduled study visits cannot take place, or arrangements need to be made to transfer trial participants who are fleeing Ukraine to other investigator sites of the same trial in the European Union (EU). Adaptations will also be needed to protect the participants' right and safety, including the continuation of ongoing trial treatment if possible, as well as to preserve the quality of the data generated by the trials. Sponsors have asked for guidance on how to handle the situation in terms of trial records, documentation, data collection, protocol deviations, and missing data with its potential impact on methodological aspects.

Where applicable, sponsors are advised to use the experience gained during the COVID-19 pandemic and apply the approaches and flexibilities agreed in this context. These are described in the following guidance documents:

- Guidance on the management of clinical trials during the COVID-19 pandemic
- Points to consider on implications of COVID-19 on methodological aspects of ongoing clinical trials

In view of the specific circumstances linked to the war in Ukraine, the Clinical Trials Coordination Group (an HMA group uniting clinical trials experts) is developing additional recommendations for sponsors. EMA will develop additional guidance on the methodological aspects of data stemming from clinical trials impacted by the war in Ukraine.

In the EU, clinical trials are authorised and supervised at national level. Sponsors are, therefore, advised to also check any available guidance at national level and to contact the relevant authorities in

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case of specific questions. Scientific advice on methodological aspects and the impact of using affected study results for regulatory purposes can be provided by EMA or the national competent authorities.

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