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Press release

Global regulators map out data requirements for phase 1 COVID-19 vaccine trials

Global regulators have published a report today presenting the outcomes of a workshop on COVID-19 vaccine development that was convened under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA).

The meeting report provides an overview of regulatory considerations related to COVID-19 vaccine development and data required for regulatory decision-making on two key points:

- Pre-clinical data required to support proceeding to first-in-human clinical trials with investigational medicinal products; and
- The need to address the known theoretical risk that vaccines against COVID-19 enhance the disease prior to starting first-in-human clinical trials.

All participants in the meeting acknowledged the urgency of conducting first-in-human clinical trials with COVID-19 vaccine candidates. The conclusions set out how regulatory authorities around the globe intend to strike the balance between rapid development of vaccines and the need to generate enough robust data to enable decision-making.

The meeting also aimed to encourage exchange of information about the global efforts towards developing new vaccines against COVID-19 through an open dialogue between medicines regulatory authorities around the globe.

About the workshop

The regulatory workshop was held virtually on 18 March 2020 in the context of the ongoing COVID-19 pandemic. It brought together delegates from 17 different countries, representing more than 20 medicines regulatory authorities globally, as well as experts from the World Health Organization and the European Commission, to share their views on the development of vaccines against COVID-19. The meeting was co-chaired by EMA and the US Food and Drug Administration (FDA).

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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