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Press release

International regulators align positions on phase 3 COVID-19 vaccine trials

Medicines regulatory authorities from around the world have published a report today highlighting the outcomes of the second workshop on COVID-19 vaccine development that was convened under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA).

The report describes the regulatory positions agreed by the meeting participants on two key topics:

- Data needed from laboratory, animal and human studies to allow initiation of phase 3 clinical trials for a COVID-19 vaccine; and
- Considerations for study design for phase 3 clinical trials.

Phase 3 is the last phase of testing of a vaccine before it can be submitted to a regulatory authority for evaluation and possible approval. The main focus of phase 3 trials is to demonstrate efficacy and safety of the vaccine.

The meeting participants stressed the need for large phase 3 clinical trials that enroll many thousands of people, including those with underlying medical conditions, to generate relevant data for the key target populations.

There was also broad agreement that clinical studies should be designed with stringent success criteria that would allow a convincing demonstration of the efficacy of COVID-19 vaccines. However, whether a vaccine would be considered as acceptable for approval is assessed case-by-case on the basis of all available data on its safety and efficacy.

About the workshop

The workshop was held to encourage regulatory convergence, to the extent possible, on certain key aspects of phase 3 clinical trial designs to help developers generate robust evidence on the quality, safety and efficacy of potential COVID-19 vaccines that meets the needs of regulators around the globe. This is critical for expediting and streamlining global development and authorisation of vaccines against COVID-19.

The workshop took place virtually on 22 June 2020. It brought together 100 delegates from more than 20 countries, representing 28 medicines regulatory authorities globally and the World Health Organization to harmonise regulatory requirements and streamline the development of COVID-19 vaccines. 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 at: www.ema.europa.eu
2. More information on the work of ICMRA can be found on its website: http://www.icmra.info/drupal/en

Contact our press officers

Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News