EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2020
EMA/338758/2020
Media and Public Relations

Press release

Global regulators discuss data requirements for phase 3 trials of COVID-19 vaccines

Under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA), international regulators discussed COVID-19 vaccine development and the necessary evidence required for regulatory decision-making at the second regulatory workshop on COVID-19 vaccines. The meeting was jointly organised by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) on 22 June 2020.

Many researchers around the world are currently working on vaccines against COVID-19 but a rapid authorisation of COVID-19 vaccines will only be possible if robust and sound scientific evidence on vaccine candidates' quality, safety and efficacy is generated. International convergence of data requirements is intended to encourage and accelerate the development of vaccines as a global public health good.

During the workshop, global regulators focused on requirements for non-clinical and clinical data from early phase studies that are needed before proceeding with advanced (phase 3) clinical trials with COVID-19 vaccine candidates in humans. They exchanged views on key aspects, such as eligibility criteria for inclusion of diverse populations, primary endpoints and other methodological considerations related to the design of phase 3 clinical trials.

Meeting participants agreed that regulatory convergence, to the extent possible, on certain key aspects of phase 3 clinical trial designs will help developers to 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 meeting built on the experience and knowledge gained from the first workshop on COVID-19 vaccine development held in March 2020, which underlined the urgency of conducting clinical trials with COVID-19 vaccine candidates in humans and international regulators' commitment to exchange information about the global efforts towards developing vaccines against COVID-19. The second workshop brought together 100 participants from more than 20 countries, representing 28 medicines regulatory authorities and the World Health Organization.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The workshop was moderated by Dr Marco Cavaleri, Head of Biological Health Threats and Vaccines Strategy at EMA, and Dr Marion Gruber, Director of Office of Vaccines Research & Review at the US FDA. More details on the discussions and the outcomes of the meeting will be shared in the coming days.

Notes

1. This press release, together with all related documents, is available on the Agency's website: www.ema.europa.eu

Contact our press officers

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