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# Global regulatory workshop on COVID-19 therapeutics #2: agreement on acceptable endpoints for clinical trials

International regulators have published a report today on the acceptability of various primary endpoints in the clinical trials conducted for the development of treatments for COVID-19.

The report summarises the main outcomes of the second workshop on COVID-19 therapeutics and clinical trials organised under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA). The workshop was co-chaired by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) and EMA on 20 July 2020.

Many developers of medicines for the treatment of COVID-19 have already or are in the process of conducting clinical trials and have approached their regulatory authorities with proposals for phase 3 clinical trials.

An agreement by regulators on acceptable endpoints will facilitate rapid and consistent implementation of future clinical trials for COVID-19 medicines across the world.

For hospitalised patients with moderate to severe COVID-19, a range of suitable primary endpoints is available to measure the clinical benefit of investigational therapeutics for COVID-19 and support regulatory decision-making. While the workshop participants agreed that mortality is not the sole acceptable primary endpoint for these patients, mortality data should still be collected as a key secondary endpoint in all trials that do not plan to primarily use this outcome.

For outpatients with mild COVID-19, regulators agreed that mortality as the primary endpoint may not be suitable. Instead, the rate of progression to severe disease and the proportion of patients not hospitalised at a pre-specified time point may be more appropriate, depending on the primary objective of the study.

The workshop was moderated by Junko Sato, Office Director of the Office of International Program at PMDA and Marco Cavaleri, Head of Biological Health Threats and Vaccines Strategy at EMA.

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