EUROPEAN MEDICINES AGENCY
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Press release

International coordination needed to encourage conduct of large, decision-relevant COVID-19 clinical trials

Regulators are highlighting the need for a comprehensive international coordination mechanism to allow the conduct of adequately powered, randomised controlled trials, which can generate sound evidence on the effects of therapeutics or vaccines against COVID-19. This follows a call made by EMA's Human Medicines Committee (CHMP) for the research community to pool resources into large, well-designed, multi-arm clinical trials to determine which investigational or repurposed medicines would be safe and effective for the treatment or prevention of COVID-19.

Although the scientific community has responded to the COVID-19 challenge in an unprecedented manner, there are concerns about the growing number of COVID-19 stand-alone clinical trials with a small number of participants and observational studies, which might not generate the data required for regulatory decision-making.

In an article published today in Clinical Pharmacology & Therapeutics, EMA authors have therefore set out concrete actions that stakeholders involved with COVID-19 clinical trials should take to generate the type of conclusive evidence needed to enable rapid development and approval of potential treatments and vaccines against COVID-19. These include:

- Research community to consider whether their planned trial can become part of a larger platform;
- Developers of COVID-19 treatments to seek interactions with regulators as early as possible;
- Support well-established public or private consortia to ramp up their activities and take on a wider role in the management of trials;
- Regulatory flexibility in clinical trial management to address challenges arising from the COVID-19 pandemic, while ensuring a high level of quality, efficacy and safety of medicines;
- Ethics committees to ensure that the benefits of conducting a stand-alone clinical trial for COVID-19 outweighs risks and burdens to the participants;
- Establish infrastructure to support clinical trial conduct;

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- Umbrella patient organisations and learned societies to use their influence to encourage clinical trial coordination.

Medicine regulatory authorities worldwide are cooperating under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA) with the aim of expediting and streamlining the development of COVID-19 vaccines and treatments. In a series of ICMRA meetings on COVID-19 held in March and April 2020, they have exchanged information about regulatory issues, including prioritisation of COVID-19 clinical trials, and sought alignment in their approaches to enhance the efficiency and effectiveness of regulatory decision-making during the current pandemic.

The article entitled "Clinical trials for Covid-19: can we better use the short window of opportunity?" is available through open access in Clinical Pharmacology & Therapeutics.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The article is co-signed by EMA staff and members of its scientific committees: Hans-Georg Eichler, Marco Cavaleri, Harald Enzmann, Francesca Scotti, Bruno Sepodes, Fergus Sweeney, Spiros Vamvakas and Guido Rasi.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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