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**Press release** 

## Call to pool research resources into large multi-centre, multi-arm clinical trials to generate sound evidence on COVID-19 treatments

EMA's Human Medicines Committee (CHMP) has published a <u>statement</u> urging the EU research community to prioritise large randomised controlled studies because they are most likely to generate the conclusive evidence needed to enable rapid development and approval of potential treatments of COVID-19. The statement promotes a harmonised approach to data collection and a robust methodology for COVID-19 clinical trials across the EU to make best use of the available supply of investigational agents. It emphasises the need to include all EU countries in these trials.

At the moment, there are no approved medicines to protect from or treat COVID-19. The CHMP has discussed the ongoing outbreak and emphasises the critical need for robust data to determine which investigational or repurposed medicinal products would be safe and effective for the treatment of COVID-19. The Committee is concerned that clinical trials with a small number of participants or compassionate use programmes might not generate the data required to draw firm conclusions on the effects of a given therapeutic and give appropriate advice to healthcare professionals and patients.

The Agency is currently engaging with different stakeholders that can further support the conduct of COVID-19 clinical trials across Europe.

EMA is ready to support medicine developers with all available regulatory tools to advance and expedite the development of effective measures to fight and prevent the spread of COVID-19. Developers of potential therapeutics or vaccines against COVID-19 are encouraged to contact the Agency as soon as possible with information about their proposed development, by emailing <a href="mailto:2019-ncov@ema.europa.eu">2019-ncov@ema.europa.eu</a>. The Agency is also supporting EU Member States by reporting to them any useful emerging information on investigational agents to treat or prevent COVID-19. EMA has mobilised a team within the Agency to work on this and the regulatory tools available to accelerate approval – as the rapid response to COVID-19 is EMA's number one priority.



## **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: <a href="https://www.ema.europa.eu">www.ema.europa.eu</a>

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