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Press release

EMA calls for high-quality observational research in context of COVID-19

For observational studies of real world data in COVID-19, EMA calls for transparency for protocols and results, and collaboration between researchers, to ensure high-quality, powerful studies. High-quality observational research of real world data collected during the pandemic can be an important complement to the results of randomised clinical trials in providing evidence on the safety and effectiveness of vaccines and treatments for COVID-19. Such research is also critical to understand how exposure to certain medicines can affect the risk or the severity of infection with the virus.

There are many ongoing observational studies by different research groups globally looking into these aspects, and there will be more in the coming months. However, to generate evidence upon which decisions can be based, observational studies of real world data must be well-designed and adequately powered (i.e. based on large populations).

When planning observational studies, researchers should adhere to existing guidelines on the appropriate design and conduct of pharmacoepidemiological studies in order to generate reliable and reproduceable evidence, including the ENCePP Guide on methodological standards in pharmacoepidemiology developed by the European Network of Centres for Pharmacoepidemiology & Pharmacovigilance (ENCePP) coordinated by EMA. EMA also reminds researchers to post all protocols and reports of observational COVID-19 studies in the EU PAS register to ensure transparency and scrutiny of study design and results.

EMA's call for high-quality observational research is complemented by a paper, Considerations for pharmacoepidemiological analyses in the SARS-CoV-2 pandemic, published recently in the journal 'Pharmacoepidemiology and Drug Safety'. The paper sets out recommendations for researchers, regulators and clinicians on how to conduct high-quality research during the pandemic.

An EMA-ENCePP COVID-19 response group has also been established as a support mechanism for high-quality observational research. The group will facilitate collaboration between researchers to improve the size and methodological rigour of studies, maximising their contribution to our knowledge of medicines' use in COVID-19.

At a recent COVID-19 workshop organised by EMA and Health Canada under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA), international regulators committed to collaboration on observational studies of real world data to increase the effectiveness and efficiency

of regulatory processes and decision-making in the development, authorisation and monitoring of medicines and vaccines to prevent and treat COVID-19 and to fill knowledge gaps that cannot be addressed by clinical trials.

A similar call was recently issued by EMA's human medicines committee (CHMP) for the research community to pool resources into large, well-designed clinical trials to determine which medicines could be safe and effective to treat COVID-19.

Notes:

- Observational studies are a fundamental part of epidemiological research. They are called observational studies because the investigator observes individuals without manipulation or intervention. This is in contrast to randomised controlled trials where investigators do intervene and look at the effects of the intervention on an outcome. Although randomised controlled trials are essential in determining causal relationships between treatment and outcome, observational studies can complement knowledge from randomised controlled trials and fill certain gaps particularly where clinical trials cannot be conducted.
- ENCePP is an EMA-coordinated initiative that brings together expertise and resources in pharmacoepidemiology and pharmacovigilance across Europe. It aims to strengthen the monitoring of the benefit-risk balance of medicinal products. This will be achieved by facilitating the conduct of high quality, multi-centre, independent post-authorisation studies (PAS) with a focus on observational research.

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