EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP/HCPWP Joint virtual meeting

2 June 2020

COVID 19 - EMA activities in relation to observational studies on use of medicines

Presented by: Xavier Kurz, Data Analytics and Methods Task Force, European Medicines Agency

An agency of the European Union

Review of real-world evidence

EUROPEAN MEDICINES AGENCY

* Interactions initiated with research groups in Europe to collect information on observational studies related to medicines use and risk and severity of Covid-19 infection

* Continuously updated tracking table of finalised, ongoing and planned observational studies (28/05)
  - **111** studies in 17 EU countries and Albania, Australia, Brazil, Brunei, Canada, China, Hong-Kong, Japan, Norway, Saudi Arabia, Singapore, South-Korea, Switzerland, Turkey, United States
  - **42** studies finalised, including studies on ACE inhibitors/ARBs, NSAIDs, HCQ, Lopinavir/Ritonavir, Ribavirin, Azithromycin, Umifenovir, Clarithromycin, Remdesivir
  - **53** studies ongoing, including studies on ACE inhibitors, ARBs, NSAIDS, HCQ, Azithromycin, Tocilizumab, Sulfasalazine, Amoxicillin, Lopinavir/Ritonavir, Darunavir
  - studies planned on different topics incl. drugs, pregnancy, special populations.

* EMA rolling review of results of observational studies to support regulatory evaluations and decision-making.

Review of real-world evidence - 2

EUROPEAN MEDICINES AGENCY

Researchers encouraged to register their studies with study protocol in the **EU PAS Register** as tool to:

- Exchange information
- Increase collaborations for multinational studies
- Support use of common protocols

www.encepp.eu

In Search function: write "COVID" in field "Title of study"

Status	EU PAS Register number	Official Title	Last Updated
Finalised	EUPAS34541	Association of ACE inhibitors and AT1R blockers and prognosis in hospitalized COVID-19 patients: a cohort study in Italy	11/05/2020
Finalised	EUPAS34753	EFFECTIVENESS AND SAFETY OF CORTICOSTEROIDS IN SARS-COV-2 INFECTION (COVID-19): COHORT STUDY	08/05/2020
Finalised	EUPAS34934	VILA-COVID 19 RETROSPECTIVE OBSERVATIONAL CLINICAL STUDY PROTOCOL: EARLY ADMINISTRATION OF CORTIC THERAPY AND ANTI-INFLAMMATORIES IN PATIENTS WITH COVID 19 DIAGNOSIS. (COVID-19)	28/04/2020
Ongoing	EUPAS35465	Multi-center, Longitudinal, Clinical Real-World Study to Evaluate Mortality and Clinical Outcomes in Hospitalized Adults with COVID-19 Infection in the United States	26/05/2020
Ongoing	EUPAS34303	A Multi-center, Multi-country Retrospective Cohort Study to Evaluate the Clinical Outcomes in Adults with Severe COVID-19	18/05/2020
Ongoing	EUPAS34663	Pharmacological risk factors for COVID-19 infection: a matched prospective cohort study of patients in primary care	18/05/2020
Ongoing	EUPAS35296	Association of angiotensin converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARB) on coronavirus disease (COVID-19) incidence and complications	14/05/2020
Ongoing	EUPAS34415	EFFECTIVENESS AND SAFETY OF TOCILIZUMAB IN INTERSTITIAL PNEUMONIA WITH SERIOUS RESPIRATORY FAILURE SECONDARY TO SARS-COV-2 INFECTION (COVID-19): COHORT STUDY	08/05/2020
Ongoing	EUPAS34756	COVID-19 IN PATIENTS WITH HEART FAILURE AND INHERITED CARDIAC CONDITIONS	08/05/2020
Ongoing	EUPAS34813	COHORTE DE PACIENTES EN TRATAMIENTO RENAL SUSTITUTIVO HOSPITALIZADOS POR COVID-19. MORTALIDAD Y FACTORES PRONÓSTICOS	23/04/2020
Ongoing	EUPAS34734	Use of non-steroidal anti-inflammatory drugs and clinical outcome of COVID-19: a Danish nationwide cohort study	21/04/2020
Ongoing	EUPAS34806	Observational study to evaluate the potential effects of biological, biosimilar, and targeted synthetic disease-modifying antirheumatic drugs in the appearance of symptoms compatible with COVID-19 infection	20/04/2020
Ongoing	EUPAS34668	Anxiety and Depression in Psychiatric Patients and Mental Health Professionals During the COVID-19 pandemic	11/04/2020
Ongoing	EUPAS34604	ASSOCIATION BETWEEN THE USE OF DRUGS IN CHRONIC PAIN AND THE INCIDENCE AND SEVERITY OF COVID-19 INFECTION: A CASE-POPULATION STUDY	07/04/2020
Ongoing	EUPAS34497	Hydroxychloroquine safety and potential efficacy as an antiviral prophylaxis in light of potential wide-spread use in COVID-19: a	03/04/2020

EMA-funded projects

EUROPEAN MEDICINES AGENCY

- **Infrastructure for COVID-19 vaccine monitoring and specific studies** on their coverage, safety and effectiveness - to be in place by Dec 2020; includes
  - list of AESIs and measurement of background rates of AESIs in same populations over >2 year period
  - templates of study protocols to speed up initiation and conduct of studies
  - contract signed 20 May
- **Framework for multicentre collaboration** for multicentre observational studies on COVID-19, inc.
  - facilitation of data access to external researchers
  - templates of study protocols
  - large multicentre proof-of-concept observational study on topic to be defined
- **Pregnancy study**
  - effects of COVID-19 infection on pregnancy outcomes
  - utilisation and effects of medications (incl. those used for COVID-19 infection) in pregnancy and effects on birth outcomes

International collaborations

EUROPEAN MEDICINES AGENCY

The **International Coalition of Medicines Regulatory Agencies (ICMRA)** will initiate collaborations for:

- Pregnancy study for 1/ better understanding of the natural history of Covid-19 in pregnancy, pregnancy outcomes and neonates, and 2/ monitoring the treatments currently used off label during pregnancy.

  This study will support regulatory decision-making on use of new therapeutics and vaccines in pregnant women.

- Building international cohorts facilitating multicentre observational studies to respond to priorities related to use/safety/effectiveness of medicines and Covid-19 disease.

- Preparation for vaccine safety monitoring to have a system ready to
  - rapidly access up-to-date data on vaccination coverage per vaccine brand
  - define AESIs and related background rates
  - agree on methods for expedited reporting of AEs and signal detection
  - quickly perform studies and ensure appropriate communication.

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

Strengthened mandate of ENCePP in the context of the COVID pandemic

Aim is to strengthen the capacity of ENCePP Centres to:

- facilitate access to high quality data and their analysis to support research and regulatory decisions in relation to the COVID-19 pandemic.
- support collaborations aiming to design and conduct high quality multicentre observational research
- improve regulatory science by promoting use and dissemination of valid and reliable methodologies appropriate to COVID-19.

ENCePP COVID-19 Response Group will be created to identify, prioritise and implementation actions as regards data access, collaborations, funding, and methodologies.

Thank you for your attention

Further information

Xavier.Kurz@ema.europa.eu

Address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Send us a question Go to www.ema.europa.eu/contact
Telephone +31 (0)88 781 6000

Follow us on **@EMA_News**