Stockholm, 23 December 2020

To: National Coordinators

Cc: National Focal Points for Viral Respiratory Diseases, National Focal Points for Vaccine-preventable Diseases, Operational Contact Points for COVID-19 (epidemiology and microbiology), Operational Contact Points for Influenza (epidemiology and microbiology)

Subject: ***Expression of interest to ECDC project monitoring COVID-19 vaccine effectiveness***

Dear National Coordinator,

In the Commission Communication of 15 October 2020, the European Commission emphasised the importance of having safe and effective COVID-19 vaccines in the EU/EEA and called on both ECDC and EMA to develop a structured post-marketing monitoring for COVID-19 vaccines.

As part of this process, we would like to inform you that ECDC is planning to conduct multicentre EU/EEA COVID-19 vaccine effectiveness monitoring studies in the EU/EEA. The roll out and the extent of the studies will be gradual, first with bridging studies which are will then be expanded in scope and planned to be continued through a multi-annual project.

As part of the initial bridging studies, ECDC has started a project through a procurement, titled "Developing an infrastructure and performing vaccine effectiveness studies for COVID-19 vaccines in the EU/EEA". The project entails working together to build and implement common EU/EEA vaccine effectiveness protocols and contribute to the pooling of EU/EEA data for vaccine effectiveness results. The protocols and studies will take into account ongoing initiatives on these topics in Europe.

The first studies to be implemented will be:

- Multi-centre vaccine effectiveness study in hospital settings
- Multi-centre vaccine effectiveness study in health care workers

To this respect, **we would like to ask you whether your country would be interested to participate in the studies**, with one or more hospitals of your country and/or by contributing with a population of health care workers, either through a hospital setting or/and another setting which allows sustainable recruitment and possibility to follow up of the individuals.

The following criteria will be considered for inclusion:

Hospital study

- EU/EEA geographic representation

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- High sample size
- COVID-19 vaccination ongoing or planned in the general population
- Previous experience with the Surveillance of Acute Respiratory Infections (SARI) in the hospital/s
- Possibility to implement a high quality data collection and validation of vaccination status (such as dates, products, number of doses), in regards to COVID-19 vaccination but also others such as influenza and pneumococcal vaccination
- Ability to contribute with individual level data to the pooled analysis
- Access to validated laboratory testing for respiratory pathogens, especially influenza (by subtype) and COVID-19. The laboratory testing should be performed according to national and international quality standards with clinically standardized and validated tests for intended use. The detection of pathogens should be performed by molecular methods, such as polymerase chain reaction. It is of advantage if the hospital/s have access to further pathogen characterisation of the positive specimens and have previous expertise in submitting characterisation data, e.g. sharing genetic sequence information on international sequence databases.

Health care workers:

- EU/EEA geographic representation
- High sample size
- COVID-19 vaccination ongoing or planned in the health care workers and/or in the general population
- Presence of previously established cohort of health care workers or previous experience with studies in health care workers
- Ability to perform a recruitment of health care workers to be followed up with regular testing, interviews/diaries and regular assessment of their health status
- Possibly to interviews/receive self-assessment of the health status of household members of in the individual taking part to the study
- Possibility to implement a high quality data collection and validation of vaccination status (such as dates, products, number of doses), in regards to COVID-19 vaccination but also others such as influenza and pneumococcal vaccination
- Ability to contribute with individual level data to the pooled analysis
- Access to validated laboratory testing for respiratory pathogens, especially influenza (by subtype) and COVID-19. The laboratory testing should be performed according to national and international quality standards with clinically standardized and validated tests for intended use. The detection of pathogens should be performed by molecular methods, such as polymerase chain reaction. It is of advantage if the hospital/s or settings have access to further pathogen characterisation of the positive specimens and have previous expertise in submitting characterisation data, e.g. sharing genetic sequence information on international sequence databases.
- Possibility to implement immunogenicity profiles in at least a subset of the cohort.

The project "Developing an infrastructure and performing vaccine effectiveness studies for COVID-19 vaccines in the EU/EEA" has been awarded to Epiconcept, who will work closely with ECDC to implement the project activities. To this respect communication regarding the activities will be via Epiconcept, in coordination with ECDC, or via the ECDC.

Following your expression of interest, ECDC will make a first high level screening and will share it with Epiconcept. Epiconcept may further contact you to define and understand the characteristics of your sites/health care workers cohorts and will propose a final list that shall be approved by ECDC, which shall be compliant with the requirements established by ECDC.

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Your expression of interest in response to this email does not represent a commitment from your side nor from ECDC side.

We would be grateful for receiving your answer by email 5.1.2e **@ecdc.europa.eu** by **Tuesday 5th January 2020**.

Yours sincerely,

Kind regards,

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on behalf of 5.1.2e 5.1.2e

5.1.2e ECDC

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