

Vaccines

## Vaccines

### OP-26E - Background Incidence Rates of Adverse Events of Special Interest for COVID-19 Vaccine Monitoring



Monday, August 23, 2021



1:45 PM – 3:30 PM US Eastern Time



Location: OP-26

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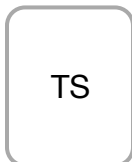
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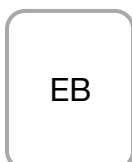
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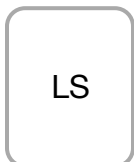
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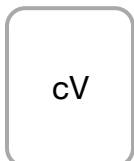
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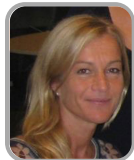
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**Background:** The global rapid spread of SARS-CoV-2 urges the development of vaccines as preventive measures to control for this pandemic. As part of the preparedness for COVID-19 vaccine monitoring, ACCESS, an EMA-funded project, has identified 37 Adverse Events of Special Interest (AESIs), including pregnancy outcomes, that may be used to monitor benefit-risk profile of COVID-19 vaccines.

**Objectives:** The overarching goal was to estimate age-and sex-stratified background incidence rates (IRs) of 37 AESIs per calendar year.

**Methods:** A retrospective multi-database dynamic cohort study was conducted from 2017 to 2020 (2010-2013 for Denmark and 2013-2017 for Germany), until the date of last data availability for each data source. The study population included all individuals observed in one of the participating data sources for at least one day during the study period and who has at least 1 year of data availability before cohort entry, except for individuals with data available since birth. Data from insurance claims (GePaRD, Germany; SNDS, France), hospitalization record linkage (PHARMO, The Netherlands; Aarhus, Denmark; FISABIO and SIDIAP, Spain; ARS, Italy) and general practitioners (Pedianet (only children), Italy; BIFAP, Spain; CPRD, UK) were included. Clinical definition forms were developed for each AESI including concept sets built from diagnosis codes and/or drug codes using 5 coding systems. The study was conducted in a distributed manner using a common protocol (EUPAS37273), common data model, and

common analytics programs. R programs for transformation of data were distributed to data access providers for local deployment. Demographic characteristics and baseline characteristics such as at-risk medical conditions for developing severe COVID-19 disease were computed for each database. Age-, sex and calendar year stratified incidence rates (95%CI) of AESIs were computed among the general population and in at-risk population.

**Results:** Evidence available on 15 February 2021 provides IRs on 26 AESI from 5 countries and 7 data sources. A total number of 20,649,121 subjects contributing to 48 million person-years were included so far, data from 3 other data sources will arrive in the coming month. IRs were stable, although some rates dropped in 2020 (e.g. cardiovascular diseases) potentially due to lock down. A clear age pattern was observed for most AESIs.

**Conclusions:** The study yielded background IRs with high precision which will be used for further assessment of the safety of COVID-19 vaccines.