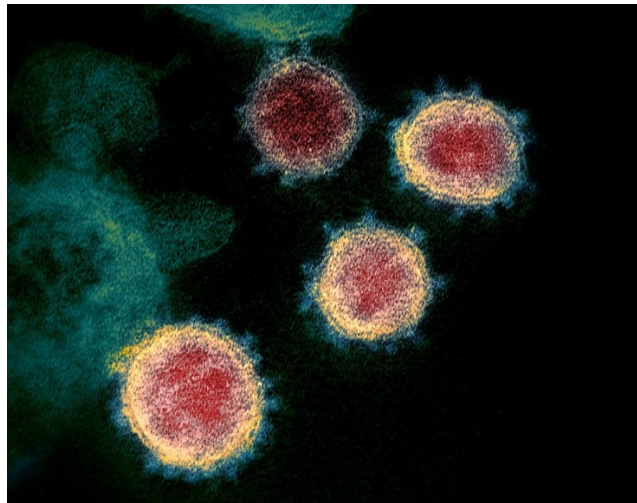# COVID-19 vaccine post-licensure effectiveness study

CASE STUDY

GIZ and P95 training

Background

For the first time, a cluster of pneumonia cases of unknown etiology was reported in Wuhan in China on 31 December 2019. On 9 January 2020, the China Center for Disease Control and Prevention reported the causative agent as being a novel coronavirus, called later severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Subsequent to China, COVID-19 underwent further geographical spread and on 11 March 2020, World Health Organization (WHO) declared COVID-19 a pandemic. Since then the COVID-19 are registered all around the world.

The high disease burden triggered the need for developing vaccines to control for pandemic. Currently there are more than 150 vaccines candidates under investigation, including RNA, DNA, inactivated and live attenuated virus vaccines. During the clinical trials each of the vaccines have demonstrated different vaccine efficacy against symptomatic disease, hospitalization or death. Several vaccines to prevent COVID-19 have granted a conditional marketing authorization and there are more to come. Due to shortage of vaccine supply, in most countries national authorities have defined and identified priority groups for vaccination - healthcare workers, the elderly and the vulnerable.

You were asked to design observational study to:

1. To estimate brand-specific vaccine effectiveness against hospitalization due to laboratory-confirmed COVID-19 who have been vaccinated with at least 1 dose and who belong to target group for vaccination.

2. To estimate brand-specific vaccine effectiveness against hospitalization due to COVID-19 who have been fully vaccinated according to the national/regional immunization recommendations and who belong to target group for vaccination.

Please discuss with you group and try to prepare the study protocol to address the above mentioned objectives.

Study design
(Please propose study design that can be used in your country)

Data sources
(What data sources are available in your country and can be used ? Indicate strengths and weaknesses of each of data sources)

Study duration
(Please provide planned study duration)

Study participants
(Please provide case definitions, inclusion and exclusion criteria)

Confounders
(Please indicate the possible confounders)

Data collection
(Please indicate how you are planning to collect the data)

Statistical analysis
(What methods will you use? How will you calculate vaccine effectiveness?)