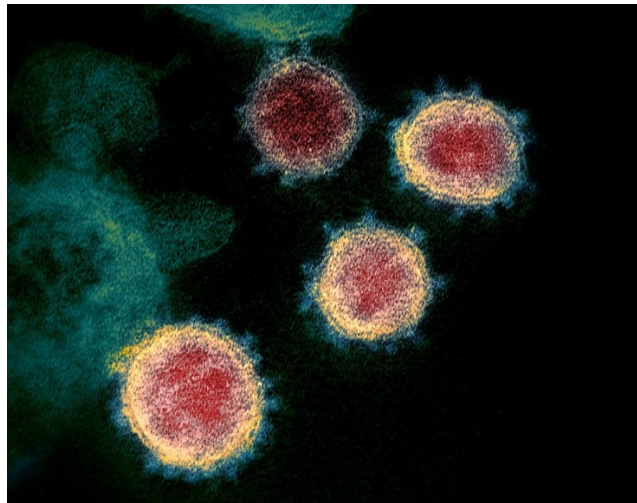# COVID-19 vaccine post-licensure safety study

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 and return to more normal life. The extraordinary effort to develop vaccine has resulted in one of the greatest achievement in vaccinology since polio vaccines. However, no medical intervention, including vaccine is fully free of adverse reactions for all people. Some of the rare serious adverse events may not be apparent until millions of vaccine doses have been administered. Ensuring vaccine safety is crucial to any vaccination program and thus post-licensure studies are needed.

You were asked to design observational study to:

1. To estimate whether there is increased risk of the pre-specified AESI following vaccination with COVID-19 vaccine.

2. To estimate whether there is increased risk of the pre-specified AESI following vaccination with the COVID-19 vaccine within risk groups of special interest.

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

Study design
(Please propose most appropriate and effective 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)

Outcomes
(Please fill the table below)

AESI	Body System /pregnancy outcome	Population	Healthcare setting	Risk window

Vaccine exposure
(How will you define exposure and collect data)

Data analysis
(What methods will you use? What measures of frequency and associations will you calculate?)