

**From:** SANTE C3 HSC  
**Sent:** vendredi 23 octobre 2020 11:00  
**To:** SANTE C3 HSC  
**Subject:** COVID-19 Vaccine Effectiveness Studies EU  
**Attachments:** COVID-19 Vaccine Effectiveness Studies EU\_final.docx

**Importance:** High

Dear Members of the Health Security Committee,

As you are aware, a large portfolio of COVID-19 vaccine candidates is being selected to accelerate their development, manufacturing and deployment. Once authorised, safety and the effectiveness of vaccines should be monitored.

The ECDC and EMA, in collaboration with the EC, Member States (NITAGs) and other partners are planning enhanced vaccine effectiveness, coverage, safety and impact monitoring activities specifically for COVID-19 vaccines.

We are sending you today a background paper with 3 questions about such post-marketing authorization studies. We plan to discuss this issue in the Health Security Committee.

Please reply to the questions by Friday 30 Oct 2020.

Kind regards,

HSC Secretariat

**Questions to the Health Security Committee:**

1. Is your country planning national / sub-national studies to monitor the safety and effectiveness of (a) COVID-19 vaccine(s), once available?
2. If yes, what kind of study/studies are you planning and what will you monitor?
  - a. Vaccination coverage
  - b. Vaccine acceptance
  - c. Safety
  - d. Effectiveness
  - e. Immunogenicity
  - f. Other things
3. Are you interested to participate in multi-country studies that would be coordinated by ECDC and EMA?