

From: EU NITAG COLLABORATION
Location: Res 525 - Video Conference Room
Importance: Normal
Subject: EU-EEA NITAG COLLABORATION WEBINAR: Follow-up Safety signal on AstraZeneca vaccine
Start Date/Time: Thur 3/18/2021 2:00:00 PM
End Date/Time: Thur 3/18/2021 3:30:00 PM
[CASE DEFINITION OF THROMBOSIS AND THROMBOEMBOLISM DRAFT.docx](#)
[SPEAC_D2.5.2.1 Thrombocytopenia Case Definition Companion Guide_V1.0 format.pdf](#)

Dear Colleagues,
Please be invited to a

**Follow-up Webinar on the Safety Signal on the AstraZeneca vaccine
Thursday 18th of March 15:00 – 16:30 CET.**

This meeting follows the EMA PRAC meeting to be held earlier on the 18th of March. Please extend the invitation to all EU/EEA NITAG Members and colleagues in public health, ministries of health and regulatory agencies with responsibilities for the COVID-19 vaccination programmes.

Please find dial-in details below.

To facilitate the EMA PRAC assessments it is key that the ADR reports submitted from MSs are of highest possible quality. It all starts with the vaccinators investigations and their reports. We discussed on the 15th of March whether a case definition would be needed to ensure reported cases are properly investigated. Although reported cases may have an atypical presentation it is possible that we can learn a lot from the earlier and on-going work by the Brighton Collaboration on case definitions. Both EMA and ECDC therefore were invited to a dialogue yesterday where the Brighton Collaboration presented their DRAFT case definition for thrombosis and thromboembolism that they have been working on since autumn 2020. Yesterday, they agreed to share the draft case definition with the EMA, EU/EEA regulators and the EU/EEA NITAG network. At the time of sending this invitation it is unclear what the outcome of the EMA PRAC assessment will be but the draft case definition may be helpful for us moving forward so we decided to share them already today for you to have a first glance. Also adding an updated Brighton Collaboration case definition on thrombocytopenia.

A very warm welcome to all.

Draft Programme

15:00 – 15:10	Welcome and objectives of the meeting	5.1.2e 5.1.2e , ECDC
15:10 – 15:40	Update on discussions and conclusions in EMA Pharmacovigilance Risk Assessment Committee concerning the safety signal on the COVID-19 vaccine AstraZeneca	5.1.2e 5.1.2e 5.1.2e 5.1.2e 5.1.2e 5.1.2e 5.1.2e , 5.1.2e 5.1.2e
15:40 – 16:00	Discussion	All
16:00 – 16:20	Next steps – need for case definition and studies?	All
16:20 – 16:30	Summary and closure of the meeting	5.1.2e 5.1.2e

**Please note that the meeting will be recorded for the purpose of the minutes.*

With kindest regards,

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ECDC Emergency Operations Centre is inviting you to a scheduled Webex meeting.

Thursday, March 18, 2021

3:00 PM | (UTC+01:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

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5.1.2h

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