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Cc: [@gesundheitsministerium.gv.at]; (PHAC/ASPC)[@canada.ca]; [@iss.it] (DGS/SP/SP1)[@sante.gouv.fr]; [@has-sante.fr]; [@nappez.com]; @ehesp.fr]; [@ordemfarmaceuticos.pt]; @salud-juntaex.es];

5.1.2e [5.1.2e @carm.es]; 5.1.2e [5.1.2e @dgs.min-saude.pt]; 5.1.2e [5.1.2e @has-sante.fr]; 5.1.2e [5.1.2e @fhi.no]; 5.1.2e [5.1.2e @oulu.fi]; 5.1.2e 5.1.2e [5.1.2e @fimea.fi]; 5.1.2e (THL)[5.1.2e @thl.fi]; 5.1.2e 5.1.2e @sciensano.be]; 5.1.2e (FAGG - AFMPS)[5.1.2e @fagg-afmps.be]; 5.1.2e [5.1.2e @fhi.no]; 5.1.2e @tuni.fi[5.1.2e @tuni.fi]; 5.1.2e [5.1.2e @aphp.fr]; 5.1.2e 5.1.2e 5.1.2e @sciensano.be]; 5.1.2e [5.1.2e @ec.europa.eu]; 5.1.2e @inrs.fr[5.1.2e @inrs.fr]; 5.1.2e [5.1.2e @mh.government.bg]; 5.1.2e @ncipd.org[5.1.2e @ncipd.org]; 5.1.2e [5.1.2e @ncipd.org]; 5.1.2e @mh.government.bg[5.1.2e @mh.government.bg]; 5.1.2e [5.1.2e @mh.government.bg]

From: EU NITAG COLLABORATION
Sent: Wed 3/31/2021 7:14:50 PM
Subject: RE: EU-EEA NITAG COLLABORATION WEBINAR: Follow-up Thromboembolic events reported following vaccination with the COVID-19 Vaccine AstraZeneca March 31 13:30 - 15:00 CET
Received: Wed 3/31/2021 7:15:16 PM
AZ vaccine monitoring.xlsx
OBJECTIVES JOHANSEN March 31, 2021.ppt

Dear Speakers,

Thank you to 5.1.2e and 5.1.2e for sharing where the PRAC review of the safety signal stands now and what the next steps expected are. EMA PRAC will reconvene April 6-9, 2021. A statement is expected at the end of this meeting and information from MSs and ECDC provided on vaccine exposure and burden of disease data by age group to EMA PRAC to inform their discussion is most appreciated.

Please also see EMA News 31/03/2021:
https://www.ema.europa.eu/en/news/astrazeneca-covid-19-vaccine-review-very-rare-cases-unusual-blood-clots-continues

Dear Participants,

Thank you for your active participation today.

Please find in attachment the most updated EU-level overview of who is recommended the AZ vaccine in respective country in addition to the opening slides for today's meeting.

Further we agreed the following during the meeting to facilitate the assessment by EMA PRAC and policy decisions in respective EU/EEA MS & UK:

1. Provide asap an overview of **EU-level burden of COVID-19 disease** reported to the ECDC TESSy database by age groups e.g. 20-39y, 20-49y and 50-59 to EMA PRAC and the EU/EEA NITAG COLLABORATION.
2. For countries with already available, or with capacity to develop, share **background rates** with EMA PRAC and EU/EEA MS & UK for CVST over a 10-year period before the COVID-19 outbreak, DIC over a 10-year period before the COVID-19 outbreak and CVST in association with COVID-19 disease from February 2020 and onwards.
3. Initiate **collaboration on work-up of affected patients and an agreed case definition** using an ECDC closed working platform EPIS with only nominated participants having access. This work will first be agreed with EMA and then invitation for nominations will be sent to the EU/EEA NITAG COLLABORATION network. Brighton Collaboration represented by 5.1.2e 5.1.2e in today's meeting has offered to support the development of a case definition using their methodology for case definitions for adverse events and contacts will be taken between EMA, ECDC and BC next week. An agreed case definition should be made urgently available to all interested in conducting pharmacoepidemiological or other studies investigating an association between CVST, DIC and vaccination with the COVID-19 Vaccine AstraZeneca or other COVID-19 vaccine.
4. Explore whether any study data on **interchangeability is available or soon will become available to guide decisions by NITAGs on what vaccine to offer for dose 2** to individuals that have received the COVID-19 Vaccine AstraZeneca for dose 1. Studies have either been initiated or are about to be initiated in Austria, Canada and the UK.

With this I would like to hand over the project leadership for the EU/EEA NITAG COLLABORATION to my ECDC colleague 5.1.2e 5.1.2e, 5.1.2e @ecdc.europa.eu and wish you best of luck with this matter and for the future. Hope to be able to follow your continued work from a distance in some capacity also moving forward.

Thanks a million for the fabulous collaboration from all of you over the last three years when this project was built up. It will now

be tested…

With kindest regards,

[redacted]

European Centre for Disease Prevention and Control (ECDC)
Gustav III:s boulevard 40, 169 73 Solna, Sweden
Phone [redacted]
www.ecdc.europa.eu

Follow ECDC on:

-----Original Appointment-----
From: EU NITAG COLLABORATION
Sent: 30 March 2021 16:46
To: EU NITAG COLLABORATION; [redacted]@sozialministerium.at'; [redacted]@meduniwien.ac.at'; [redacted]@stpierre-bru.be'; [redacted]@sciensano.be'; [redacted]@hzjz.hr'; [redacted]@stampar.hr'; [redacted]; [redacted]@cytanet.com.cy'; [redacted]@szu.cz'; [redacted]@szu.cz'; [redacted]@sst.dk'; [redacted]@ssi.dk'; [redacted]@sm.ee'; [redacted]@terviseamet.ee'; [redacted]@thl.fi'; [redacted]; [redacted]@santepubliquefrance.fr'; [redacted]@rki.de'; [redacted]@uni-ulm.de'; [redacted]@med.uoa.gr'; [redacted]@gmail.com'; [redacted]@nnk.gov.hu'; [redacted]@olchc.ie'; [redacted]@hotmail.com'; [redacted]@hse.ie'; [redacted]@sanita.it'; [redacted]@apollo.lv'; [redacted]@spkc.gov.lv'; [redacted]@sam.lt'; [redacted]@sam.lt'; [redacted]@ms.etat.lu'; [redacted]@ms.etat.lu'; [redacted]@gov.mt'; [redacted]@gov.mt'; [redacted]@rivm.nl'; [redacted]@gr.nl'; [redacted]@fhi.no'; [redacted]@fhi.no'; [redacted]@pzh.gov.pl'; [redacted]@pzh.gov.pl'; [redacted]@dgs.min-saude.pt'; [redacted]@dgs.min-saude.pt'; [redacted]@arsnorte.min-saude.pt'; [redacted]@ms.ro'; [redacted]@insp.gov.ro'; [redacted]@insp.gov.ro'; [redacted]@uvzsr.sk'; [redacted]@jfmed.uniba.sk'; [redacted]@nijz.si'; [redacted]@nijz.si'; [redacted]@mscbs.es'; [redacted]@mscbs.es'; [redacted]@phe.gov.uk'; [redacted]@phe.gov.uk; [redacted]@folkhalsomyndigheten.se'; [redacted]@ncipd.org'; [redacted]@landlaeknir.is'; [redacted]@landlaeknir.is'; [redacted]@libero.it'; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]@ema.europa.eu'; [redacted]@ema.europa.eu'; [redacted]@ec.europa.eu'; [redacted]; [redacted]; [redacted]; [redacted]@folkhalsomyndigheten.se'; [redacted]@llv.li'; [redacted]; [redacted]; [redacted]; [redacted]; ([redacted]@iss.it)'; [redacted]@iss.it'; [redacted]@guest.iss.it'; [redacted]@iss.it'; [redacted]; [redacted]; [redacted], [redacted]; [redacted]@who.int
Cc: [redacted]; [redacted] (PHAC/ASPC); [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted] (FAGG - AFMPS); [redacted]; [redacted]@tuni.fi; [redacted]; [redacted]@inrs.fr; [redacted]; [redacted]@ncipd.org; [redacted]; [redacted]@mh.government.bg; [redacted]
Subject: EU-EEA NITAG COLLABORATION WEBINAR: Follow-up Thromboembolic events reported following vaccination with the COVID-19 Vaccine AstraZeneca March 31 13:30 - 15:00 CET
When: 31 March 2021 13:30-15:00 (UTC+01:00) Belgrade, Bratislava, Budapest, Ljubljana, Prague.
Where: Webex/EOC 525

Dear Colleagues,

Please be invited to an urgent **webinar on**

Follow-up Thromboembolic events reported following vaccination with the COVID-19 Vaccine AstraZeneca (Vaxzevria)

Wednesday 31 March 13:30 - 15:00 CET

Some background reading:

https://assets.researchsquare.com/files/rs-362354/v1/ebd0055b-50ad-4a8e-9d42-b967d0d8b132.pdf

https://www.n-tv.de/panorama/Berlin-sperrt-Astrazeneca-fuer-alle-unter-60-Jaehrigen-article22460840.html

https://www.theguardian.com/world/2021/mar/30/canada-suspends-use-of-astrazeneca-covid-vaccine-for-those-under-55

Please also extend the invitation to EU/EEA NITAG Members and colleagues in public health, ministries of health or regulatory agencies with responsibilities for the COVID-19 vaccination programmes.

Dial-in details below.

A very warm welcome to all.

Draft Programme

13:30 – 13:35	Welcome and objectives of the meeting	5.1.2e
13:35 – 13:50	Update from EMA expert meeting on the Astra Zeneca vaccine TE signal held 29 March, 2021 and next steps planned by EMA/PRAC	5.1.2e 5.1.2e 5.1.2e 5.1.2e
13:50 – 14:15	Questions and answers	All
14:15 – 14:55	Discussion - Are age restrictions needed? - Implications for the 2nd dose? - Need for observational studies/other studies?	All
14:55 – 15:00	Next steps	5.1.2e ECDC colleagues

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

With kindest regards,

5.1.2e
5.1.2e
EU/EEA NITAG COLLABORATION

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

Wednesday, March 31, 2021

1:30 PM | (UTC+02:00) Brussels, Copenhagen, Madrid, Paris | 1 hr 30 mins

Join meeting

More ways to join:

Join from the meeting link

5.1.2h

Join by meeting number

Meeting number (access code): 5.1.2h

Meeting password: 5.1.2h

Tap to join from a mobile device (attendees only)

5.1.2h Sweden Toll International Dial

gium Toll

Some mobile devices may ask attendees to enter a numeric password.

Join by phone

5.1.2h Sweden Toll International Dial

5.1.2h Belgium Toll

Global call-in numbers

Join from a video system or application

Dial 5.1.2e @ecdc.webex.com

You can also dial 5.1.2h and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 5.1.2h @lync.webex.com

Need help? Go to https://help.webex.com