To: 5.1.2e @rki.de'[5.1.2e @rki.de]; 5.1.2e (5.1.2e @thl.fi)'[5.1.2e @thl.fi]; 5.1.2e 5.1.2e [5.1.2e @rivm.nl]; 5.1.2e @mscbs.es'[5.1.2e @mscbs.es]; 5.1.2e @nijz.si'[5.1.2e @nijz.si]
Cc: 5.1.2e [5.1.2e @ecdc.europa.eu]; 5.1.2e [5.1.2e @ecdc.europa.eu]; 5.1.2e [5.1.2e @ecdc.europa.eu]
From: 5.1.2e
Sent: Mon 3/22/2021 1:54:20 PM
Subject: FW: ECDC-EMA proposal for Joint Advisory Board Safety and Effectiveness studies
Received: Mon 3/22/2021 1:55:08 PM
ECDC-EMA joint COVID-19 vaccine monitoring platform - JAB mandate FINAL.docx

Dear Steering Committee members,

We are very happy to announce that the collaboration between EMA and ECDC is taking another step forward.

To support the collaboration between the agencies, please find below an invitation to join the EMA/ECDC advisory board. For you to understand more what this could entail and how many it could involve we are proposing to have a call in the very near future. 5.1.2e or 5.1.2e will come back to us all responding to this e-mail.

With kindest regards,

5.1.2e

5.1.2e
5.1.2e
Air-Borne, Blood-Borne and Sexually Transmitted Infections, DPR
Phone +46 5.1.2e
5.1.2e @ecdc.europa.eu

European Centre for Disease Prevention and Control (ECDC)
Gustav III:s boulevard 40, 169 73 Solna, Sweden
Phone + 5.1.2e
www.ecdc.europa.eu

Follow ECDC on:

From: 5.1.2e < 5.1.2e @ecdc.europa.eu>
Sent: 16 March 2021 12:53
To: 5.1.2e < 5.1.2e @ecdc.europa.eu>
Cc: 5.1.2e < 5.1.2e @ecdc.europa.eu>; 5.1.2e < 5.1.2e @ecdc.europa.eu>
Subject: ECDC-EMA proposal for Joint Advisory Board Safety and Effectiveness studies
Importance: High

Dear 5.1.2e

Attached is the proposed (almost final) terms of reference of the joint EMA/ECDC advisory board for safety and effectiveness studies. This was sent to the Director for final approval (see email below).

From ECDC, we are proposing that the most suitable representatives based on the terms of the collaboration are members of the NITAG SC.

We trust this will be of interest to them and will allow a platform for exchange between licensing and public health authorities. This may prove indeed very useful and in particular for the current situation with the AZ vaccine safety signal.

Here the scope/purpose of the board and main elements in bold:

- *The JAB is established by the two Agencies in the context of post-authorisation surveillance activities foreseen to monitor the performance of COVID-19 vaccines in real-life settings. In line with the respective mandates of the two Agencies, EMA will be responsible for monitoring the safety, and ECDC the effectiveness, of these vaccines.*
- *The JAB is primarily established as a **consultative body**, and is **not expected to fulfil a decisional nor operational***

function *with regards to the implementation of the safety and effectiveness studies coordinated by the two Agencies.*

- ***At regular intervals*** *(Remark: 2 meeting planned in 2021 so far in April and October but can be increased upon need), the JAB will be presented with, and* ***invited to provide advice*** *on:*
    - *ongoing studies*
    - *preliminary and interim findings/results*
    - *challenges faced in the implementation of the studies,*
    - *and considerations for future plans.*

- *As such, the JAB is expected to provide a* ***forum for exchange and discussion****. The JAB may also be asked to provide guidance on operational aspects related to the implementation of the studies, where needed. The proposal is for the JAB to comprise representatives from relevant* ***national regulatory and public health authorities operating at EU and national level****. Leveraging the JAB to create such* ***bridge between the regulatory and public health dimensions*** *is considered critical to inform relevant discussions and developments concerning vaccine products as well as vaccination strategies.*

5.1.2e and myself would be grateful if you would introduce this to the NITAG SC and ask for their agreement to be nominated as part of this board. We feel you are best to write to the SC.

A first meeting of the board is planned to be held towards the end of April.

Thank you for your help

Kind regards

5.1.2e

5.1.2e
5.1.2e
Air-Borne, Blood-Borne and Sexually Transmitted Infections (ABS), DPR
Room number 5.1.2e / Extension 5.1.2e

From: 5.1.2e < 5.1.2e @ecdc.europa.eu>
Sent: 16 March 2021 11:04
To: Director < 5.1.2e @ecdc.europa.eu>
Cc: 5.1.2e < 5.1.2e @ecdc.europa.eu>; 5.1.2e < 5.1.2e @ecdc.europa.eu>; 5.1.2e 5.1.2e < 5.1.2e @ecdc.europa.eu>; 5.1.2e < 5.1.2e @ecdc.europa.eu>
Subject: Revision of ECDC-EMA proposal for Joint Advisory Board Safety and Effectiveness studies
Importance: High

Dear DIR colleagues,

We would like to put to 5.1.2e kind attention this email and the document here attached concerning the collaboration between ECDC and EMA on the set-up of a Joint Advisory Board for the conduct of safety and effectiveness studies for COVID-19 vaccines. This document specifically relates to the need to create a grouping of Member State representatives from across public health and regulatory to meet, as relevant, in order to provide EMA and ECDC with a form of non-binding advice on the studies the two agencies are coordinating. We have worked with EMA to come up with this draft over the past few weeks.

We would now need to share this with SANTE as agreed with them in an earlier coordination call, but we would like 5.1.2e to revise it and approve it from her side/give us any comments based on which we should adapt our approach for this Board. EMA's Director has already given their green light on the document. Internally, at ECDC, the document has also been revised and approved by 5.1.2e

Would it be possible to let us know 5.1.2e s feedback as soon as feasible for her agenda? EMA would like to share this with 5.1.2e by Thursday this week if possible.

Many thanks in advance for your kind attention.

Warm regards,
5.1.2e

5.1.2e
5.1.2e
Air-Borne, Blood-Borne and Sexually Transmitted Infections, DPR
Room number : 5.1.2e