

With warmest regards,

5.1.2e

5.1.2e

5.1.2e

Air-Borne, Blood-Borne and Sexually Transmitted Infections, DPR

Phone 5.1.2e
5.1.2e @ecdc.europa.eu <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 / Fax 5.1.2e

www.ecdc.europa.eu <http://www.ecdc.europa.eu>

Follow ECDC on: <http://www.facebook.com/ECDC.EU> <http://twitter.com/ecdc_eu>
<http://www.linkedin.com/company/ecdc> <http://www.youtube.com/user/ECDCchannel>

-----Original Message-----

From: 5.1.2e <5.1.2e@rki.de>

Sent: 24 November 2020 16:21

To: 5.1.2e (SCHN) <5.1.2e@health.nsw.gov.au>; 5.1.2e (PHAC/ASPC) <5.1.2e@canada.ca>; EU NITAG
COLLABORATION <5.1.2e@ecdc.europa.eu>; 5.1.2e @fhi.no>; 5.1.2e
<5.1.2e@rivm.nl>; 5.1.2e @lf3.cuni.cz' <5.1.2e@lf3.cuni.cz>; 5.1.2e @ssi.dk' <5.1.2e@ssi.dk>;
<5.1.2e@itg.be' <5.1.2e@itg.be>; 5.1.2e @rki.de>; 5.1.2e (5.1.2e@thi.fi'
<5.1.2e@thi.fi>; 5.1.2e @who.int' <5.1.2e@who.int>

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>; 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>; 5.1.2e
<5.1.2e@ecdc.europa.eu>; 5.1.2e <5.1.2e@rki.de>; 5.1.2e <5.1.2e@rki.de>

Subject: AW: EU/EEA NITAG Collaboration WG 3 - LSR on COVID-19 vaccines - Protocol and TOR for comments

Dear all,

please find attached the revised version of the protocol. A few explanations:

- 1) Investigation of immunogenicity would go far beyond the scope of our review and beyond the resources we can invest here. In addition, immunogenicity is captured in a Cochrane Review which will be conducted by Cochrane France for WHO.
- 2) With regard to safety outcomes, this also applies to Phase 1/2 studies.
- 3) We changed the starting date to 01 January 2021.

Please have a look and send any final comments by tomorrow (25 Nov).

Best,

5.1.2e

-----Ursprüngliche Nachricht-----

Von: 5.1.2e (SCHN) <5.1.2e@health.nsw.gov.au>

Gesendet: Dienstag, 24. November 2020 09:35

An: 5.1.2e (PHAC/ASPC) <5.1.2e@canada.ca>; EU NITAG COLLABORATION

<5.1.2e@ecdc.europa.eu>; 5.1.2e @fhi.no>; 5.1.2e
<5.1.2e@rivm.nl>; 5.1.2e @lf3.cuni.cz' <5.1.2e@lf3.cuni.cz>; 5.1.2e @ssi.dk' <5.1.2e@ssi.dk>; 5.1.2e @itg.be'
<5.1.2e@itg.be>; 5.1.2e @rki.de>; 5.1.2e @rki.de>; 5.1.2e
(5.1.2e@thi.fi' <5.1.2e@thi.fi>; 5.1.2e @who.int' <5.1.2e@who.int>

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>; 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>; 5.1.2e
<5.1.2e@ecdc.europa.eu>

Betreff: RE: EU/EEA NITAG Collaboration WG 3 - LSR on COVID-19 vaccines - Protocol and TOR for comments

Sorry for not being able to respond sooner. I've just got 2 suggestions, tracked over [redacted] latest version with other's comments.

Kind regards,

[redacted]

From: [redacted] (PHAC/ASPC) [redacted]@canada.ca]
 Sent: Tuesday, 24 November 2020 3:11 PM
 To: EU NITAG COLLABORATION <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@fni.no>;
 [redacted] <[redacted]@itg.be>; [redacted] <[redacted]@itg.be>; [redacted] <[redacted]@rvm.nl>; [redacted] <[redacted]@lf3.cuni.cz>; [redacted] <[redacted]@lf3.cuni.cz>; [redacted] <[redacted]@ssi.dk>; [redacted] <[redacted]@ssi.dk>;
 [redacted] <[redacted]@thl.fi>; [redacted] <[redacted]@thl.fi>; [redacted] <[redacted]@rki.de>; [redacted] <[redacted]@rki.de>; [redacted] <[redacted]@thl.fi>; [redacted] <[redacted]@thl.fi>; [redacted] <[redacted]@health.nsw.gov.au>; [redacted] <[redacted]@who.int>
 <[redacted]@who.int>
 Cc: [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>
 Subject: RE: EU/EEA NITAG Collaboration WG 3 - LSR on COVID-19 vaccines - Protocol and TOR for comments

Some minor comments to consider are attached.

Thanks!

[redacted]

[redacted]
 [redacted] Centre for Immunization and Respiratory Infectious Diseases / Centre de l'immunisation et des maladies respiratoires infectieuses Public Health Agency of Canada / Agence de la santé publique du Canada [redacted]@canada.ca
 <[redacted]@canada.ca>
 [redacted]

From: EU NITAG COLLABORATION <[redacted]@ecdc.europa.eu>
 <[redacted]@ecdc.europa.eu>
 Sent: 2020-11-23 11:55 AM
 To: [redacted] <[redacted]@fni.no>; [redacted] <[redacted]@fni.no>; [redacted] <[redacted]@rvm.nl>; [redacted] <[redacted]@rvm.nl>; [redacted] <[redacted]@lf3.cuni.cz>; [redacted] <[redacted]@lf3.cuni.cz>; [redacted] <[redacted]@lf3.cuni.cz>; [redacted] <[redacted]@ssi.dk>; [redacted] <[redacted]@ssi.dk>; [redacted] <[redacted]@itg.be>; [redacted] <[redacted]@itg.be>; [redacted] <[redacted]@itg.be>; [redacted] <[redacted]@rki.de>; [redacted] <[redacted]@rki.de>; [redacted] <[redacted]@rki.de>; [redacted] <[redacted]@thl.fi>; [redacted] <[redacted]@thl.fi>; [redacted] <[redacted]@thl.fi>; [redacted] <[redacted]@thl.fi>; [redacted] <[redacted]@thl.fi>; [redacted] <[redacted]@thl.fi>; [redacted] <[redacted]@health.nsw.gov.au>; [redacted] <[redacted]@health.nsw.gov.au>; [redacted] <[redacted]@who.int>; [redacted] <[redacted]@who.int>
 Cc: [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>; [redacted] <[redacted]@ecdc.europa.eu>
 Subject: RE: EU/EEA NITAG Collaboration WG 3 - LSR on COVID-19 vaccines - Protocol and TOR for comments

Dear [redacted] and members of the WG3,

Please find my proposed edits in the attached document. Please also consider to follow the template made last year for the influenza vaccine SR to be found here: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=156800
<https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=156800>

I do note that there are a number of suggestions from WG members, which is highly appreciated, and I am wondering if you would be able to review proposed edits and update the protocol and resend it out for a final view of those that wish to see it once more, like me. [redacted] will come with some last comments tomorrow morning and then the ECDC comments are done.

With kindest regards,

[redacted]

From: [redacted] <[redacted]@fhi.no> <[redacted]@fhi.no> >
Sent: 23 November 2020 13:56
To: [redacted] <[redacted]@rivm.nl> <[redacted]@rivm.nl> >; [redacted] <[redacted]@f3.cuni.cz>
<[redacted]@f3.cuni.cz> <[redacted]@f3.cuni.cz> >; [redacted] <[redacted]@ssi.dk> <[redacted]@ssi.dk> >; [redacted] <[redacted]@itg.be>
<[redacted]@itg.be> <[redacted]@itg.be> >; [redacted] <[redacted]@rki.de> <[redacted]@rki.de> >; [redacted] <[redacted]@thl.fi> <[redacted]@thl.fi> >; [redacted] <[redacted]@thl.fi> <[redacted]@thl.fi> >; [redacted] <[redacted]@canada.ca> <[redacted]@canada.ca> >
<[redacted]@canada.ca> >; [redacted] <[redacted]@health.nsw.gov.au> <[redacted]@health.nsw.gov.au> >
<[redacted]@health.nsw.gov.au> >; [redacted] <[redacted]@who.int> <[redacted]@who.int> >; EU NITAG
COLLABORATION <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >
Cc: [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >
<[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >
<[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >
<[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >
Subject: SV: EU/EEA NITAG Collaboration WG 3 - LSR on COVID-19 vaccines - Protocol and TOR for comments

Dear WG3 members and observers

I hereby send my comments and notes to the LSR.

I have used the same document as [redacted] and [redacted]

Thank you

Best regards

Fra: [redacted] <[redacted]@rivm.nl> <[redacted]@rivm.nl> >
Sendt: søndag 22. november 2020 14:52
Til: [redacted] <[redacted]@f3.cuni.cz> <[redacted]@f3.cuni.cz> >; [redacted] <[redacted]@ssi.dk> <[redacted]@ssi.dk> >; [redacted] <[redacted]@fhi.no> <[redacted]@fhi.no> >; [redacted] <[redacted]@itg.be>
<[redacted]@itg.be> <[redacted]@itg.be> >; [redacted] <[redacted]@rki.de> <[redacted]@rki.de> >; [redacted] <[redacted]@thl.fi> <[redacted]@thl.fi> >; [redacted] <[redacted]@thl.fi> <[redacted]@thl.fi> >; [redacted] <[redacted]@canada.ca> <[redacted]@canada.ca> >
<[redacted]@canada.ca> >; [redacted] <[redacted]@health.nsw.gov.au> <[redacted]@health.nsw.gov.au> >
<[redacted]@health.nsw.gov.au> >; [redacted] <[redacted]@who.int> <[redacted]@who.int> >; EU NITAG
COLLABORATION <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >
Kopi: [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >
<[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >; [redacted] <[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >
<[redacted]@ecdc.europa.eu> <[redacted]@ecdc.europa.eu> >

Also as a side note if you have not seen it already, FYI a link to this Lancet paper published today on Safety and immunogenicity of ChAdOx1 nCoV-19 vaccine administered in a prime-boost regimen in young and old adults(COV002): a single-blind, randomised, controlled, phase 2/3 trial: <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2932466-1>

We look forward to hearing from you soon.

Thank you.

Kind regards,

5.1.2e & 5.1.2e

On behalf of the

EU/EEA NITAG Collaboration Secretariat

European Centre for Disease Prevention and Control (ECDC) Gustav III:s boulevard 40, 169 73 Solna, Sweden

Phone +46 (0)8 5.1.2e / Fax +46 (0)8 5.1.2e

www.ecdc.europa.eu <<http://www.ecdc.europa.eu>>

Follow ECDC on:

<<http://www.facebook.com/ECDC.EU>>

<http://twitter.com/ecdc_eu>

<<http://www.linkedin.com/company/ecdc>>

<<http://www.youtube.com/user/ECDCchannel>>

Confidentiality Notice

If you are not the intended recipient of this message, you are hereby kindly requested, to, consecutively, refrain from disclosing its content to any third party, delete it, and inform its sender of the erroneous transmittal.

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.
www.rivm.nl <<http://www.rivm.nl/>> De zorg voor morgen begint vandaag

This message may contain information that is not intended for you. If you are not the addressee or if this message was sent to you by mistake, you are requested to inform the sender and delete the message. RIVM accepts no liability for damage of any kind resulting from the risks inherent in the electronic transmission of messages.
www.rivm.nl/en <<http://www.rivm.nl/en/>> Committed to health and sustainability

Confidentiality Notice

If you are not the intended recipient of this message, you are hereby kindly requested, to, consecutively, refrain from disclosing its content to any third party, delete it, and inform its sender of the erroneous transmittal.

This message is intended for the addressee named and may contain confidential information. If you are not the intended recipient, please delete it and notify the sender.

Views expressed in this message are those of the individual sender, and are not necessarily the views of NSW Health or any of its entities.

Confidentiality Notice

If you are not the intended recipient of this message, you are hereby kindly requested, to, consecutively, refrain from disclosing its content to any third party, delete it, and inform its sender of the erroneous transmittal.