

**To:** [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] (SCHN) [redacted] [redacted] @health.nsw.gov.au; [redacted] [redacted] (PHAC/ASPC) [redacted] [redacted] @canada.ca; EU NITAG COLLABORATION [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @fhi.no; [redacted] [redacted] [redacted] [redacted] @rivm.nl; [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] [redacted] [redacted] @rki.de; [redacted] [redacted] [redacted] [redacted] @thl.fi; [redacted] [redacted] @thl.fi; [redacted] [redacted] @who.int; [redacted] [redacted] @who.int

**Cc:** [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @rki.de; [redacted] [redacted] [redacted] [redacted] @rki.de

**From:** [redacted] [redacted] [redacted]

**Sent:** Thur 11/26/2020 9:52:44 AM

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

**Received:** Thur 11/26/2020 9:53:00 AM

Dear [redacted]

thank you very much. A few questions/suggestions from my end:

- 1) collaborators: could you please send me a list with affiliations and email addresses so I can copy/paste them into the protocol
- 2) settings: I suggest that we also assess such studies since it appears hard to me where to draw the line here - would we, for instance, not include a large well-controlled cohort study that has been performed in the US or Australia? To take into account possible variability of effectiveness due to setting, I suggest to stratify results by geography and setting.
- 3) we will explicitly include narcolepsy
- 4) We will take up [redacted] suggestion and name it thromboembolism.
- 5) Meta-analysis is explained under 28. Sorry, I forgot to tick the box, as well as the one for vaccines.

Happy to explain and discuss next week. Please send me the list as mentioned under 1) and I will finalize and submit the protocol.

Best,

[redacted]

-----Ursprüngliche Nachricht-----

Von: [redacted] [redacted] <[redacted]@ecdc.europa.eu>

Gesendet: Mittwoch, 25. November 2020 22:10

An: [redacted] [redacted] <[redacted]@rki.de>; [redacted] [redacted] (SCHN) <[redacted]@health.nsw.gov.au>; [redacted] [redacted] (PHAC/ASPC) <[redacted]@canada.ca>; EU NITAG COLLABORATION <[redacted]@ecdc.europa.eu>; [redacted] [redacted] [redacted] [redacted] @fhi.no; [redacted] [redacted] [redacted] [redacted] @rivm.nl; [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] [redacted] [redacted] @rki.de; [redacted] [redacted] [redacted] [redacted] @thl.fi; [redacted] [redacted] @thl.fi; [redacted] [redacted] @who.int; [redacted] [redacted] @who.int

Cc: [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @ecdc.europa.eu; [redacted] [redacted] [redacted] [redacted] @rki.de; [redacted] [redacted] [redacted] [redacted] @rki.de

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

Dear [redacted]

Minor comments below:

- E-mails must be provided for each collaborator
- Point 15 does not include EU authorised COVID-19 vaccines, I think COVID should be in capital letters everywhere in the text
- Point 23 you write all possible settings, does this mean in any country across the world? Or is it hospital, out-patient etc? Not sure we want to include studies from any country if effectiveness for example would be much lower in a setting very different from Europe such as the case is for rotavirus vaccines
- Point 24, please note that I do not think narcolepsy is in the CEPI criteria but has been added both by EMA, and US CDC Immunisation safety office. I strongly advise to include narcolepsy.
- Point 25 I think [redacted] named it thromboembolism instead of stroke and thrombosis, which should include stroke, pulmonary embolism and deep vein thrombosis. We also have the paediatric entity COVID-19-Associated Multisystem Inflammatory Syndrome which is rare but little Sweden has had 70 such cases since onset of the outbreak

Are we not doing any meta-analysis?

Health area of review - not sure vaccines is ticked?

Great that we got so many comments. In the upcoming meeting you may want to address why you did not include some of the suggestions. One of them I was thinking of is the selection of ROBINS-I instead of NOS which the new people on board this time may wish to hear.

With warmest regards,

5.1.2e

5.1.2e 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 <5.1.2e@rki.de>

Sent: 24 November 2020 16:21

To: 5.1.2e 5.1.2e (SCHN) <5.1.2e@health.nsw.gov.au>; 5.1.2e 5.1.2e (PHAC/ASPC) <5.1.2e@canada.ca>; EU NITAG  
COLLABORATION <5.1.2e@ecdc.europa.eu>; 5.1.2e 5.1.2e 5.1.2e <5.1.2e@fhi.no>; 5.1.2e 5.1.2e  
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 5.1.2e <5.1.2e@rki.de>; 5.1.2e 5.1.2e (5.1.2e@thl.fi)  
<5.1.2e@thl.fi>; 5.1.2e @who.int' <5.1.2e@who.int>

Cc: 5.1.2e 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 <5.1.2e@ecdc.europa.eu>; 5.1.2e 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 <5.1.2e@ecdc.europa.eu>; 5.1.2e 5.1.2e  
<5.1.2e@ecdc.europa.eu>; 5.1.2e 5.1.2e <5.1.2e@rki.de>; 5.1.2e 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 5.1.2e (SCHN) <5.1.2e@health.nsw.gov.au>

Gesendet: Dienstag, 24. November 2020 09:35

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

<5.1.2e@ecdc.europa.eu>; 5.1.2e 5.1.2e 5.1.2e <5.1.2e@fhi.no>; 5.1.2e 5.1.2e 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 5.1.2e <5.1.2e@rki.de>; 5.1.2e 5.1.2e <5.1.2e@rki.de>; 5.1.2e 5.1.2e  
(5.1.2e@thl.fi)' <5.1.2e@thl.fi>; 5.1.2e @who.int' <5.1.2e@who.int>

Cc: 5.1.2e 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 <5.1.2e@ecdc.europa.eu>; 5.1.2e 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 <5.1.2e@ecdc.europa.eu>; 5.1.2e 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]@fhi.no>;  
 [redacted]@rivm.nl>; [redacted]@lf3.cuni.cz' <[redacted]@lf3.cuni.cz>; [redacted]@ssi.dk' <[redacted]@ssi.dk>;  
 [redacted]@itg.be' <[redacted]@itg.be>; [redacted]@rki.de>; [redacted]@rki.de>; [redacted]@thl.fi' <[redacted]@thl.fi>;  
 [redacted] (SCHN) <[redacted]@health.nsw.gov.au>; [redacted]@who.int' <[redacted]@who.int>  
 Cc: [redacted]@ecdc.europa.eu>; [redacted]@ecdc.europa.eu>; [redacted]@ecdc.europa.eu>; [redacted]@ecdc.europa.eu>; [redacted]@ecdc.europa.eu>; [redacted]@ecdc.europa.eu>; [redacted]@ecdc.europa.eu>; [redacted]@ecdc.europa.eu>; [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]@fhi.no <[redacted]@fhi.no>; [redacted]@rivm.nl <[redacted]@rivm.nl>; [redacted]@lf3.cuni.cz' <[redacted]@lf3.cuni.cz>; [redacted]@ssi.dk' <[redacted]@ssi.dk>; [redacted]@itg.be' <[redacted]@itg.be>; [redacted]@rki.de <[redacted]@rki.de>; [redacted]@thl.fi <[redacted]@thl.fi>; [redacted] (PHAC/ASPC) <[redacted]@canada.ca <[redacted]@canada.ca>>; [redacted]@health.nsw.gov.au' <[redacted]@health.nsw.gov.au <[redacted]@health.nsw.gov.au>>; [redacted]@who.int' <[redacted]@who.int >>  
 Cc: [redacted]@ecdc.europa.eu <[redacted]@ecdc.europa.eu>>; [redacted]@ecdc.europa.eu <[redacted]@ecdc.europa.eu>>; [redacted]@ecdc.europa.eu <[redacted]@ecdc.europa.eu>>; [redacted]@ecdc.europa.eu <[redacted]@ecdc.europa.eu>>; [redacted]@ecdc.europa.eu <[redacted]@ecdc.europa.eu>>; [redacted]@ecdc.europa.eu <[redacted]@ecdc.europa.eu>>; [redacted]@ecdc.europa.eu <[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)  
<[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. 5.1.2e will come with some last comments tomorrow morning and then the ECDC comments are done.

With kindest regards,

5.1.2e

From: 5.1.2e <5.1.2e@fhi.no> <5.1.2e@fhi.no> >  
Sent: 23 November 2020 13:56  
To: 5.1.2e <5.1.2e@rivm.nl> <5.1.2e@rivm.nl> >; 5.1.2e <5.1.2e@lf3.cuni.cz> <5.1.2e@lf3.cuni.cz> >; 5.1.2e <5.1.2e@ssi.dk> <5.1.2e@ssi.dk> >; 5.1.2e <5.1.2e@itg.be> <5.1.2e@itg.be> >; 5.1.2e <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@thl.fi> <5.1.2e@thl.fi> >; 5.1.2e <5.1.2e@canada.ca> <5.1.2e@canada.ca> >; 5.1.2e <5.1.2e@health.nsw.gov.au> <5.1.2e@health.nsw.gov.au> >; 5.1.2e <5.1.2e@who.int> <5.1.2e@who.int> >; EU NITAG COLLABORATION <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >  
Cc: 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@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 5.1.2e and 5.1.2e

Thank you

Best regards

5.1.2e

Fra: 5.1.2e <5.1.2e@rivm.nl> <5.1.2e@rivm.nl> >  
Sendt: søndag 22. november 2020 14:52  
Til: 5.1.2e <5.1.2e@lf3.cuni.cz> <5.1.2e@lf3.cuni.cz> >; 5.1.2e <5.1.2e@ssi.dk> <5.1.2e@ssi.dk> >; 5.1.2e <5.1.2e@fhi.no> <5.1.2e@fhi.no> >; 5.1.2e <5.1.2e@itg.be> <5.1.2e@itg.be> >; 5.1.2e <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@thl.fi> <5.1.2e@thl.fi> >; 5.1.2e <5.1.2e@canada.ca> <5.1.2e@canada.ca> >; 5.1.2e <5.1.2e@health.nsw.gov.au> <5.1.2e@health.nsw.gov.au> >; 5.1.2e <5.1.2e@who.int> <5.1.2e@who.int> >; EU NITAG COLLABORATION <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >  
Kopi: 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >  
<5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >

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

Please find some remarks.

Regards, 5.1.2e

From: 5.1.2e @lf3.cuni.cz <5.1.2e@lf3.cuni.cz> <5.1.2e@lf3.cuni.cz> <5.1.2e@lf3.cuni.cz> <5.1.2e@lf3.cuni.cz>  
 Sent: zaterdag 21 november 2020 16:22  
 To: 5.1.2e @ssi.dk' <5.1.2e@ssi.dk> <5.1.2e@ssi.dk> >; 5.1.2e @fhi.no' <5.1.2e@fhi.no> <5.1.2e@fhi.no> >; 5.1.2e @rivm.nl <5.1.2e@rivm.nl> >;  
 <5.1.2e@fhi.no> <5.1.2e@fhi.no> >; 5.1.2e @itg.be' <5.1.2e@itg.be> <5.1.2e@itg.be> >;  
 <5.1.2e@itg.be> >; 5.1.2e @rki.de <5.1.2e@rki.de> <5.1.2e@rki.de> >; 5.1.2e @rki.de <5.1.2e@rki.de> >;  
 <5.1.2e@rki.de> >; 5.1.2e @thl.fi <5.1.2e@thl.fi> <5.1.2e@thl.fi> >; 5.1.2e @thl.fi <5.1.2e@thl.fi> >;  
 <5.1.2e@thl.fi> >; 5.1.2e @canada.ca' <5.1.2e@canada.ca> <5.1.2e@canada.ca> >;  
 <5.1.2e@canada.ca> >; 5.1.2e @health.nsw.gov.au' <5.1.2e@health.nsw.gov.au> <5.1.2e@health.nsw.gov.au> >; 5.1.2e @who.int' <5.1.2e@who.int> <5.1.2e@who.int> >; EU NITAG COLLABORATION <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >  
 Cc: 5.1.2e @ecdc.europa.eu <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e @ecdc.europa.eu <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e @ecdc.europa.eu <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >;  
 <5.1.2e@ecdc.europa.eu> >; 5.1.2e @ecdc.europa.eu <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >;  
 <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e @ecdc.europa.eu <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >;  
 <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >; 5.1.2e @ecdc.europa.eu <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >;  
 <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >

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

Dear WG3 members and observers

I send my comments and notes to the LSR.

Thank you

Best regards

5.1.2e

On 19. 11. 2020 16:18 +0100, EU NITAG COLLABORATION <5.1.2e@ecdc.europa.eu> <5.1.2e@ecdc.europa.eu> >, wrote:

Dear WG 3 members and observers

Thank you very much for all of you who were able to join the meeting on Wednesday, we managed to hold a fruitful meeting even with the IT hiccups!

Please find attached to this email:

- \*The protocol for the LSR
- \*The Terms of Reference for the WG 3
- \*Brief minutes from the kick-off meeting

Could you please provide any suggested changes or comments using track changes to the LSR protocol document and the Terms of Reference document by Monday 23rd November COB.

We will send out a Doodle shortly to schedule the second meeting.

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

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