From: [redacted]@mscbs.es
To: EU NITAG COLLABORATION
Cc: [redacted]@mscbs.es; [redacted]@mscbs.es
Subject: RE: Request for INFORMATION - ongoing heterologous prime/boost COVID-19 vaccine trials
Date: 25 May 2021 18:30:59
Attachments: image001.gif
image002.png
image003.png
image004.png
image005.png
Supplementary appendix_v5_only protocol SAP.PDF

Dear colleagues,

Please find the responses below in red and the protocol of the study attached.

- Type of combination studied (e.g. vaccines studied and sequence): Administration of Comirnaty in subjects previously vaccinated with one dose of Vaxzevria at least 8 weeks before
- Planned trial period: one year (including laboratory research with the samples obtained)
- Trial participants: 600 subjects younger than 60 years, previously vaccinated with one dose of Vaxzevria
- Primary and secondary study endpoints: 1) analyze the increment of antibodies against SARS-CoV-2 14 days after the administration of one dose of Comirnaty; 2) analyze the reactogenicity of the heterologous scheme

If at all feasible, please kindly share any relevant information by Tuesday 25 May end-of-day, in order to be incorporated into the presentation.
https://www.isciii.es/Noticias/Noticias/Paginas/Noticias/PresentacionEnsayoCombivacs.aspx
https://www.isciii.es/Noticias/Noticias/Paginas/Noticias/Presentaci%c3%b3n-resultados-preliminares-CombivacS.aspx

kind regards,

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De: EU NITAG COLLABORATION [mailto:EU.NITAG.COLLABORATION@ecdc.europa.eu]
Enviado el: lunes, 24 de mayo de 2021 17:08
Para: [redacted]

[redacted]
CC: EU NITAG COLLABORATION; [redacted]
Asunto: Request for INFORMATION - ongoing heterologous prime/boost COVID-19 vaccine trials

Dear Colleagues -

On Wednesday 26 may 2021, our team at ECDC is requested to provide an update on "Heterologous combinations of vaccine doses for COVID-19 (so-called "mix and match" studies) as part of a Health Security Committee (HSC) meeting. The HSC focal point(s) in your country may have informed you.

While preparing for this, we understand that we are lacking a comprehensive overview of ongoing or planned "mix and match studies".

Would you kindly take a few minutes to indicate of ongoing and or planned studies in your country that you may be aware of and that are investigating the safety, immunogenicity and/or efficacy of COVID-19 vaccine in a mixed schedule?

Information that would be relevant to receive include:

- Type of combination studied (e.g. vaccines studied and sequence)
- Planned trial period
- Trial participants
- Primary and secondary study endpoints

If at all feasible, please kindly share any relevant information by Tuesday 25 May end-of-day, in order to be incorporated into the presentation.

We would kindly acknowledge your contribution.

Best regards,
[redacted]

ECDC VPI Team

ECDC Logo

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