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From: [REDACTED]
Sent: Mon 1/11/2021 6:55:42 PM
Subject: FW: ACTION required by all members before January 12, 5 pm CET regarding VAC4EU Moderna request (takes 1-10 minutes)
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[Modernaproposal20201223_v0.1.pdf](#)

Ter info

From: [REDACTED] <[REDACTED]@vac4eu.org>
Sent: zondag 10 januari 2021 22:25
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Subject: ACTION required by all members before January 12, 5 pm CET regarding VAC4EU Moderna request (takes 1-10 minutes)

Dear VAC4EU members

We hope you had a good holiday and welcome back to the COVID-19 vaccine reality, let's hope immunization goes smoothly. I wish you all a very good 2021!

As you know we rapidly submitted a VAC4EU proposal to Moderna on Dec 23 (see enclosed) based on a conversation we had Dec 22. Moderna mentioned this document was used in their discussions with EMA on Dec 29. Their RMP now states they will do a EU PASS, it does not yet state who will do it.

We had a follow-up call with Moderna and they asked us to do a feasibility assessment from all members/data access providers to EHR data. They particularly wish to know about the lag times of data for rapid assessment and the ability to look at pregnancy outcomes.

We will need to submit an updated proposal that will have a staged approach by January 15 this will have the following elements

- 1) Rapid assessment of AESI with ecological approach, repeatedly in DAPs with short lag time (interrupted time series of AESI incidence), no need to be able to link to vaccine
- 2) Subsequent evaluation with self-controlled designs where possible if something comes up this can also be done in larger group of DAPs, requirement to be able to assess vaccine brand
- 3) Pregnancy outcomes and child follow-up, this again may be done in separate group of DAPs

We have prepared a surveymonkey for this request which will take one minute to complete to assess roles from all members, and maximum ten minutes for organizations with access to EHR data. Please click on this link for completion

<https://www.surveymonkey.com/r/B3T7J6H>



We would like everybody on this mail to complete the survey by January 12. Results will be summarised for Moderna. Moderna also wishes a budget estimate which requires us to decide on roles and responsibilities, Teamit will follow-up on this with a separate request

Please note, It is not yet clear whether this proposal will go ahead. IQVIA is the competitor and already has a framework agreement. But let's see what we can do. I feel that access to good pregnancy outcome data will be crucial and of course our expertise.

Thank you very much for your support

Best regards,

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