To: (10)(2e) [(10)(2e)@rivm.nl]; (10)(2e) [(10)(2e)@rivm.nl]
Sent: Fri 10/30/2020 9:48:34 AM
Subject: FW: SC03 ACCESS safety protocols & Update on ACCESS activities and opportunities for ROC19
Received: Fri 10/30/2020 9:48:31 AM
COVID-19 Hospital Based Safety_Protocol Template_ Draft_28Oct2020.docx
ACCESS Protocol Safety (10)(2e) v0.3_30OCT2020.docx

Ter info!

From: (10)(2e). <(10)(2e)@umcutrecht.nl>
Sent: vrijdag 30 oktober 2020 10:40
To: (10)(2e)@clin.au.dk' <(10)(2e)@clin.au.dk>; (10)(2e)@clin.au.dk' <(10)(2e)@clin.au.dk>; (10)(2e)@aemps.es' <(10)(2e)@aemps.es>; (10)(2e)@agemed.es' <(10)(2e)@agemed.es>; (10)(2e)@aemps.es' <(10)(2e)@aemps.es>; (10)(2e)@aemps.es' <(10)(2e)@aemps.es>; (10)(2e)@aemps.es' <(10)(2e)@aemps.es>; (10)(2e)@aemps.es' <(10)(2e)@aemps.es>; (10)(2e)@aemps.es' <(10)(2e)@aemps.es>; (10)(2e)@ars.toscana.it' <(10)(2e)@ars.toscana.it>; (10)(2e)@ars.toscana.it' <(10)(2e)@ars.toscana.it>; (10)(2e)@leibniz-bips.de' <(10)(2e)@leibniz-bips.de>; (10)(2e)@leibniz-bips.de' <(10)(2e)@leibniz-bips.de>; (10)(2e)@icf.uab.cat' <(10)(2e)@icf.uab.cat>; (10)(2e)@icf.uab.cat' <(10)(2e)@icf.uab.cat>; (10)(2e)@gva.es' <(10)(2e)@gva.es>; (10)(2e)@gmail.com' <(10)(2e)@gmail.com>; (10)(2e)@fisabio.es' <(10)(2e)@fisabio.es>; (10)(2e)@gmail.com' <(10)(2e)@gmail.com>; (10)(2e)@gva.es' <(10)(2e)@gva.es>; (10)(2e)@idiapjgol.org' <(10)(2e) (10)(2a) (10)(2e)@lareb.nl' <(10)(2e)@lareb.nl>; (10)(2e)@lareb.nl' <(10)(2e)@lareb.nl>; (10)(2e)@lareb.nl' <(10)(2e)@lareb.nl>; (10)(2e)@pharmo.nl' <(10)(2e)@pharmo.nl>; (10)(2e)@pharmo.nl' <(10)(2e)@pharmo.nl>; (10)(2e)< (10)(2e)@rivm.nl>; (10)(2e)< (10)(2e)@rivm.nl>; (10)(2e)@rti.org' <(10)(2e)@rti.org>; (10)(2e)@rti.org' <(10)(2e)@rti.org>; (10)(2e)@rti.org' <(10)(2e)@rti.org>; (10)(2e)@rti.org' <(10)(2e)@rti.org>; (10)(2e)@rti.org' <(10)(2e)@rti.org>; (10)(2e)@rti.org' <(10)(2e)@rti.org>; (10)(2e)@sciensano.be' <(10)(2e)@sciensano.be>; (10)(2e)@unipd.it' <(10)(2e)@unipd.it>; (10)(2e)@phd.unipd.it' <(10)(2e)@phd.unipd.it>; (10)(2e). <(10)(2e)@umcutrecht.nl>; (10)(2e). <(10)(2e)@umcutrecht.nl>; (10)(2e). <(10)(2e)@umcutrecht.nl>; (10)(2e), (10)(2e). <(10)(2e)@umcutrecht.nl>; (10)(2e)@u-bordeaux.fr' <(10)(2e)@u-bordeaux.fr>; (10)(2e)@u-bordeaux.fr' <(10)(2e)@u-bordeaux.fr>; (10)(2e)@u-bordeaux.fr' <(10)(2e)@u-bordeaux.fr>; (10)(2e)@unime.it' <(10)(2e)@unime.it>; (10)(2e)@unime.it' <(10)(2e)@unime.it>; (10)(2e)@unime.it' <(10)(2e)@unime.it>; (10)(2e)@unime.it' <(10)(2e)@unime.it>; (10)(2e)@farmasi.uio.no' <(10)(2e)@farmasi.uio.no>; (10)(2e)@farmasi.uio.no' <(10)(2e)@farmasi.uio.no>; (10)(2e)@uu.nl' <(10)(2e)@uu.nl>; (10)(2e)@uu.nl' <(10)(2e)@uu.nl>; (10)(2e)@uu.nl' <(10)(2e)@uu.nl>; (10)(2e)@uu.nl' <(10)(2e)@uu.nl>; (10)(2e)@uu.nl' <(10)(2e)@uu.nl>; (10)(2e)@uu.nl' <(10)(2e)@uu.nl>; (10)(2e)@uu.nl' <(10)(2e)@uu.nl>; (10)(2e)@skynet.be' <(10)(2e)@skynet.be>; (10)(2e)@deplazio.it' <(10)(2e)@deplazio.it>; (10)(2e)@deplazio.it' <(10)(2e)@deplazio.it>; (10)(2e)@unipd.it' <(10)(2e)@unipd.it>; (10)(2e)@unipd.it' <(10)(2e)@phd.unipd.it>; (10)(2e)@univr.it' <(10)(2e)@univr.it>; (10)(2e)@sciensano.be; (10)(2e)@sciensano.be' <(10)(2e)@sciensano.be>
Subject: SC03 ACCESS safety protocols & Update on ACCESS activities and opportunities for ROC19
Importance: High

Dear ACCESS contributors
I am very happy to share with you the two safety protocols that were created by RTI-HS and my colleagues at UMCU. They have been sent to (10)(2a) and I truly believe both of them are very important pieces of work that will guide the monitoring of COVID_19 vaccine safety. For now the protocols are still confidential, so please do not share further. As soon as they are endorsed by (10)(2a) they will be made public. Nov 6, they will be discussed with the advisory committee of (10)(2a) Nov 16 they will need to be resubmitted and will undergo external consultation.

I would like to take this opportunity to update you also on other work that is ongoing around vaccine monitoring preparedness

- the two ACCESS effectiveness protocols have been updated based on the first level of (10)(2a) review by RTI-HS and FISABIO and will now go out for external stakeholder consultation.

Several other important activities are ongoing:

- the DAPs will have important work this month to implement the VGR protocol, this includes conduct of ETL, run the scripts for BGR and generate results, deadline for the report to (10)(2a) is Dec 15, and we hope to have some countries in the results. We propose weekly meetings to share progress and issues that may occur. Meeting invites will be sent by (10)(2e) and (10)(2e) The task management system that many of you know through ConcePTION will be used to manage the tasks ahead. The SAP following the pipeline is drafted and will be finalized in the coming weeks.

- Two other protocols: coverage (UMCU) and app-based monitoring (LAREB) are also in preparation, and a methods description (UU) of how to integrate B/R.

- In November we will reach out to all the organizations in Europe that indicated in the survey they would be willing to participate to one or more of the studies, and feasibility needs to be assessed. This work is conducted by VAC4EU, anybody who would like to support this work is very welcome. This would mean calling organizations and assessing feasibility, there a total of 50 beyond us. Our current thinking is to organize country webinars for countries that have many sites such as (10)(2a) and (10)(2a) . It would be great to build relations so that we are all ready to collaborate when vaccines get introduced, we also need to see what the training needs would be

It is amazing what this group has been doing in these hectic times with little funding. I know we are doing excellent and important work to have (10)(2a) prepared. I am happy to announce you that the BGR protocol has been adopted as the basis of the Global Vaccine Data Network protocol on BGR, and also FDA CBER will use it analyse data in BEST. We are in contact with (10)(2a) (10)(2a) to align with the V_SAFE (app based approach) and the codes for EHR work

We do not yet know who will be paying/contracting for the implementation of the protocols. We have seen the first request from (10)(2a) ROC19, to implement the app-based work in a cohort event monitoring, deadline of submission Nov 6. The current thinking is to develop 3 WP

1. Cohort event monitoring using the work that LAREB has been developing with several of the partners
2. Near real time monitoring based on EHR data, this is like done in ADVANCE, datasources with lag times less than 2-4 weeks can participate, please indicate if that would be possible
3. Coordination, legal and privacy

We will start developing the proposal for this application, (10)(2e) has asked for interest, please send her a mail if you wish to participate in this tender, and in which WP, anybody not already being a subcontractor/partner we need a letter of intent.
Important is also if your organization would be able to reach out to health care workers, and can ask them to use the app, these will be the first groups to be targeted. So please let us know, PEDIANET could access a big group of primary care physicians, those working in hospitals could ask support to roll out in their organization.

For implementation of other ACCESS protocols, we will need to wait. (10)(2a) are discussing with the European Commission and they cannot share yet, I assume there will be public tendering of safety and effectiveness monitoring, but vaccine manufacturers will also need to do studies.
The call with Vaccines Europe this week was revealing. In spite of the co-creation of VAC4EU in ADVANCE many of the vaccine manufacturers are still reluctant. It is uncertainty about capacity, scaling, and lack of control. We have had strong discussion in the VAC4EU Ex. Board, and propose the following:

1. Listing of organizations capacity and experience on the VAC4EU website (for members): we will extract this from membership forms and send to you for approval
2. Starting a campaign through linkedin and create more visibility
3. Just continue to deliver good work and show our strength!

All of this is not possible without your dedication, excellence and participation thanks a lot! I feel we are doing very

important work to implement COVID-19 vaccine monitoring, currently 10 products are in phase 3, so they come available rapidly.

With kind regards,

(10)(2e) (10)(2e)

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Verzonden: vrijdag 30 oktober 2020 9:44
Aan: (10)(2e) (10)(2e))
CC: (10)(2e) (10)(2e) (10)(2e)
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Onderwerp: SC03 ACCESS safety protocols (draft)
Urgentie: Hoog

Dear (10)(2e)

Please find attached the two **ACCESS safety protocols (draft)** for discussion with the EMA monitoring committee on **Friday, 6 November 2020 at 16h00.**

- Hospital Case–Based Monitoring of Specific Adverse Events Following COVID-19 Vaccines: A Protocol Template
- Monitoring safety of COVID-19 vaccines in healthcare databases: a protocol template

Regarding the **timelines**; would it be possible to receive any written comments from the experts by **Monday, 9 November** so that the task leads have some time to revise the protocols before they are submitted for EMA review on 16 November, as agreed previously?

We are looking forward to our discussion next week,

Best regards,
(10)(2e)

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