

2) DAPs to submit the protocol to obtain local governance approval soonest. In order to have expedited review please indicate that this study is urgently requested by EMA pointing to the following announcement [https://www.ema.europa.eu/en/news/ema-commissions-independent-research-prepare-real-world-](https://www.ema.europa.eu/en/news/ema-commissions-independent-research-prepare-real-world)

### [monitoring-covid-19-vaccines](#)

Please send a mail to (10)(2e) (10)(2e) [@umcutrecht.nl](mailto:(10)(2e)@umcutrecht.nl) by Oct 1 when the governance review will be done or otherwise that it is not needed.

3) **DAPs that have not yet designed an ETL** towards the ConcePTION CDM (e.g. Pedianet) should set an appointment with (10)(2e) to schedule an appointment for an interview by Oct. 5 COB (10)(2e) [@ars.toscana.it](mailto:(10)(2e)@ars.toscana.it)

4) **Definitions and Code lists** for the events have been created, and can be reviewed for each of the definitions on a public google drive. (10)(2g)

We would like DAPs to verify codes and make comments online by **October 12** if they wish especially if they have experience extracting these events

### **Information for everyone**

#### **SAP**

The SAP for the BGR protocol is drafted and will be sent for review October 5

#### **Tools**

- Sharepoint access login will be provided in coming week
- DRE access will be organised in coming weeks and credentials will be sent by VAC4EU sec
- Task management system is set up to have easier management of requests to DAPs

#### **Survey to assess organizational capacity**

VAC4EU has launched the survey to assess country capacity. This is distributed through ENCePP (done today), PRAC (done by EMA), IMI-DRIVE, EU-JAV, and hopefully through WHO-EURO or ECDC.

The Link is available on the VAC4EU website and can also be shared with anyone you wish in Europe. Please forward. The initial survey is short and will be followed by dedicated protocol specific surveys.

<https://www.surveymonkey.com/r/VK79LTL>

As partners please fill out as well, and you will also be receiving follow-up surveys

Please let us know if you have access to eastern European networks or relevant contacts, as they seem to be missing. Aim of the survey is to be very geographically comprehensive

#### **October 7 discussion of effectiveness protocols with EMA**

We have monthly meetings with the EMA advisory committee to discuss output and receive input. on October 7 the two effectiveness protocols will be discussed with EMA, thank you FISABIO and RTI-HS for drafting them.

In November we aim to discuss the safety protocols.

#### **Website**

The VAC4EU website has been updated and contains information on the webinars and what we are doing.

**Presentation**

the project has been presented to the IMI-DRIVE annual forum.

**Contracts**

the administrative hurdles at UMCU have been cleared and subcontracts should be signed next week for those who are subcontracted through u and sent a partially signed contract.

We wish you all a good weekend please let us know whether you have any question

Best regards,

On behalf of the project leads,

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

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*Denk s.v.p. aan het milieu voor u deze e-mail afdrukt.*

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