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From: 5.1.2e
Sent: Wed 11/25/2020 2:09:46 PM
Subject:
Received: Wed 11/25/2020 2:12:37 PM
RFP COVID-19 vaccine signal detection_final version.docx

Dear VAC4EU members

Apologies for a very long, but important and urgent mail.

I would like to notify you about very good news: We have contracted with teamit research (5.1.1d 5.1.2e), which will support the process of requests for studies for VAC4EU, which is just in time! Welcome 5.1.2e 5.1.2e and 5.1.2e . They will support all steps around business development and outreach as well as relations with requesting partners until the contract is signed with one of the members of VAC4EU.

Another good news is that VAC4EU is also partner in the EMA tender ROC19, to support early monitoring of COVID-19 vaccines for EMA, this project has been awarded yesterday and will start December and run till November 2021, many of you may p

articipate.

COVID-19 vaccines are moving rapidly and so do the requests to conduct studies. We have received two requests for studies in the past days, with very short turn-around times, as the companies need to create their RMPs and first approvals may be done mid-december.

Requests to VAC4EU are

1) A RFP from Vaccines Europe (the collective of vaccine manufacturers) asking for cohort event monitoring to detect signals for COVID-19 vaccines, in the UK and Europe. Deadline Dec 3. This is primary data collection (see attached)

2) A dedicated request from Pfizer to submit a proposal to use electronic health care records for monthly monitoring of AESI. This is through secondary use of available health data that can be linked to vaccinations. This follows after several TCs

These requests overlap with the work that will be done for EMA by some of you and we have discussed with 5.1.2e whether this is a concern. For EMA this is not a conflict. Organizations can work both for EMA as well as for vaccine manufacturers, in fact EMA requires manufacturers to do studies and endorses them to use VAC4EU. However, we cannot be paid twice for generating the same data, or in other words EMA will not pay for the part that is paid by private organizations, we will be able to address this but it should not be a concern for you to participate

We have had many discussions in the past two days about strategy and we would like to share the following

For the Vaccines Europe RFP (number 1)

The UK part will be done by DSRU, that wishes to work together with VAC4EU and also become member. They have a protocol almost ready that they will share these days and we hope is aligned with ACCESS protocol developed by LAREB that will be used for EMA

Basic design: cohort of vaccinated individuals enrolled upon vaccination, with specific vaccine, provide e-consent, and are followed up periodically. DSRU has 1,5,12,26 wks and 24 months of follow-up. People may choose to respond by app or be phoned (esp elderly). In case of non-response next of kin is called. For all SAE the GP will be contacted and needs to be paid to provide details. Inclusion is in nursing homes, occupational health departments in hospitals for health care workers and GP for the 'at risk populations' or with the mass campaign coordinators. Most costs/effort will be in MedDRA coding the AEs. The sample size required is not stated, but as VAC4EU core we feel we need to propose at least 60000 per brand, to be at least twice as big as the trials and propose the ENCePP CoC. The 60K can come from multiple countries but should reflect the target populations.

We are urgently looking for:

1) **Coordinating site EU**. The coordinator should be able to write the RFP with teamit and DSRU in the coming days and be able to take on the contractual and subcontracting obligations if the bid is successful.
    a. Given the questions that are asked we would prefer a coordinating organization that is well acquainted with clinical trials and primary data collection, and used to work and 'price; for companies.
    b. Please let us know by thursday Nov 26 5 pm whether your organization would be interested to take this role.
2) **Understanding** which data collection tools are quickly available/accessible through members (apps & call centers) for use in any of the organizations. If you have tools available that can be used in multiple sites for data collection from patients let us know sending a description/link and the contact person by Nov 26 5 pm.
3) Which members would be willing to implement the cohort event monitoring protocols and be willing to act as a study site in their country. Please let us know by Nov 26 5 pm. Those sites should be able to provide information on how they would implement the study reaching the target populations, and what the cost would be by Monday Nov 30, 5 pm, you will receive a template for this, but please start thinking and discussing
4) For all potential participants we will organize briefing call on Friday Nov 27 and Tuesday Dec.1.

For the Pfizer proposal (number 2)

Basic design: cohort study of target population people, EHR data linked to receipt of Pfizer vaccine. Outcomes: AESI for which we also do background rates.

We are looking for

1) **Coordinating site**. The coordinator should be able to write the RFP with teamit in the coming days and be able to take on the contractual and subcontracting obligations if the bid is successful.
    a. Given the questions that are asked we would prefer a coordinating organization that has experience in coordinating multisite studies using EHR data, and with the ConcePTION CDM/pipeline
    b. Please let us know by thursday Nov 26 5 pm whether your organization would be interested to take this role.
2) **Understand** whether you have access to data that can be provided monthly that would allow for the conduct of

the study and your country will use the Pfizer vaccine. Please provide information on the data source Nov 26 5 pm.

3) Which organizations would be willing to provide either

   a. Programming of the R tools that would apply the design and generate the estimate

   b. Data management support for pooling and reporting/dashboard. Please let us know by Nov 26 5 pm.

4) Participating organizations will receive a template from teamit to collect details on methods, data, costs and CVs on Nov 27, this should be filled by Dec 1.

5) For all potential participants to this we will organize a briefing call, we need to assess when.

Please do not forward this mail outside of your organizations

Best regards and thank you very much for your rapid attention to this

Please reply by mail to 5.1.2e @teamitresearch.com and 5.1.2e @vac4eu.org

5.1.2e & 5.1.2e