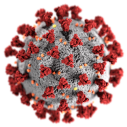
ACCESS
vACCine covid-19  monitoring readinESS

VAC4EU
VAccine monitoring Collaboration for Europe

Briefing Book

Goal

The ACCESS project has as goal to prepare a European infrastructure for the monitoring of the COVID-19 vaccines and for conducting specific studies in a collaborative manner across EU countries.

What is ACCESS?

ACCESS is a project that is currently funded with public money through the European Medicines Agency with the aim to create readiness in Europe to monitor the novel COVID-19 vaccines, post-introduction. The project started May 20, 2020 and ends in December 2020. By December 2020 a system and protocols should be in place for the conduct of studies that will be requested from public or private organizations (e.g. vaccine manufacturers).

Background to a collaborative EU ecosystem for vaccine monitoring

The 2009 pandemic taught us that collaboration between stakeholders is necessary to monitor vaccine coverage, benefits and risks in Europe. This need was described in a recent paper as a statement from different stakeholders in Europe.
Based on the lessons learned from the 2009 pandemic the Innovative Medicines Initiative funded the ADVANCE project in 2013 which aimed to design and tested an ecosystem for monitoring of the coverage, benefits and risks of vaccines. The project ended in 2019 and led to the Blueprint (written by ECDC) and the creation of the VAC4EU non-for-profit international association as a sustainable solution for collaboration between research organizations and public health institutes.

The Vaccine monitoring Collaboration for Europe (VAC4EU) was established as legal entity in October 2019 and provides an ecosystem (member organizations, people capacity, data access, methods and IT infrastructures) to allow for robust and transparent European collaboration on vaccine coverage, benefits and risk monitoring. It supports primary data collection and secondary use of existing data. Because of the availability of VAC4EU, ACCESS can build on governance and design of the ecosystem as governance solution for execution of the studies on COVID-19 in Europe.

VAC4EU is open for membership from all non-publicly listed organizations in Europe. Members can coordinate and conduct studies, together, using the infrastructures that have been tested and are available for use by all members.

Deliverables from the ACCESS project

1) A protocol for the generation of background rates of AESI in at least 7 countries Description of the data sources
2) Lists of AESI and the codes and algorithms for identification plus benchmark incidence rates from the literature.
3) Template protocols for the following studies which may be possible using different sources of data and therefore possible for each country.

Hospital-based studies (primary data collection)

- Case-based studies to assess safety. Cases can be retrieved in hospital and studies are self-controlled. Requirement is that vaccine history can be obtained.
- Prospective monitoring of COVID-19 vaccine effectiveness using a test negative design

Patient-based safety monitoring

- Prospective monitoring of COVID-19 safety using apps that are completed by vaccine recipients

Electronic health record data

- Retrospective assessment of the safety of COVID-19 vaccines using available EHR data
- Retrospective monitoring of COVID-19 vaccine effectiveness using available EHR data in Europe

Immunization registries

- Retrospective monitoring of coverage of COVID-19 vaccines based on immunization registries/data sources

Protocols will be submitted to EMA in a batchwise manner, reviewed by an advisory committee to EMA and opened for dedicated stakeholder input.

Opportunities to contribute

VAC4EU will organize the following opportunities for input from the scientific community

- Questions and answer webinars open to all type of organizations:
  - August 13,
  - October 15.
- Scientific discussions on specific pharmacoepidemiological topics relevant for COVID-19
  - September 10, How to assess vaccine mediated enhanced disease in epidemiological studies
  - November 12. How to measure exposure to COVID-19 vaccines
- VAC4EU members and ACCESS consortium members can input on all protocols.
- Input from organizations with memoranda of understanding with VAC4EU (DRIVE, SPEAC & Global Vaccine Data Network)

How will we identify sites that might be able to participate in studies post-introduction?

We will identify sites able to implement each of the studies to be delivered to EMA in December 2020 in each of the member states

With the aim to allow all members states to participate and be prepared to monitor vaccines we will reach out to identify capacity and organizations that would be able to participate in any or all of the collaborative EU studies in each of the member states through

- PRAC members
- ENCePP sites
- IMI-DRIVE sites
- EU joint action for vaccines

Collaboration with ECDC and outreach through advisory forum is under discussion. Organizations may also self-refer to be willing to participate.

Governance for conduct of studies

The ACCESS project will create preparedness and identify sites but EMA is not funding the implementation of the protocols through that contract. Implementation may be requested by vaccine manufacturers or public entities (e.g. ECDC, EMA, EC) after vaccines are introduced.

Template protocols prepare that studies may be implemented rapidly according to the established governance principles of the Vaccine monitoring Collaboration for Europe (VAC4EU) which has a well-defined governance with articles of association and bylaws. VAC4EU itself does not conduct studies, it functions as a matchmaker between study requesters and its network.
The VAC4EU secretariat (secretariat@vac4eu.org) can be contacted by any study requesters. The studies will be coordinated by member organizations, who will contract with the study requester and subcontract to the other participating organizations.

The operations structure for the execution of post-licensure vaccine studies:

1) Study requesters (public or vaccine manufacturers) can contact the VAC4EU secretariat with a request for proposal (RFP) and the desired Code of Conduct
   ENCePP CoC
   ADVANCE CoC
   The key difference between the two codes is the level of participation of a person employed by an organization with a commercial, financial or institutional interest in the study.
2) VAC4EU secretariat will share the RFP with the member organizations and inquire about interest to participate, roles, capacities, desired responsibilities. A coordinating center will be agreed by the members.
3) The VAC4EU secretariat will respond to the study requester and reach agreements

4) Once the coordinating center is agreed and the participating organizations, the coordinating center will estimate costs, and contract with the study requester and subcontract participating organizations
5) VAC4EU secretariat will provide access to infrastructure (Tools, templates, IT)

Questions

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