VAC4EU: a pan-European research network for collaborative post-authorisation vaccine safety and benefit monitoring

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Background

VAC4EU (Vacccine monitoring Collaboration for Europe) is a not-for-profit international association with 25 member organisations specialised in the collaborative generation of real-world evidence on coverage, safety, and efficacy of vaccines in Europe. VAC4EU was established as a result of the IMI-ADVANCE project with the aim to enable, coordinate and accelerate the creation of the best evidence at European level on vaccine effects. In the past two years, VAC4EU has proven preparedness and efficiency in designing post-authorisation monitoring for COVID-19 vaccines responding to the requests of both the European Medicines Agency (EMA) and vaccine manufacturers.

Objectives

To describe the VAC4EU organization, data, tools and the accomplishments made towards the generation of real-world evidence on vaccine benefit-risk evaluation.

Results

Since its creation in October 2019, VAC4EU has established a research network composed of 25 institutions from 9 European countries (BE, DE, DK, FR, IT, NL, NO, ES, UK) providing access to 15 health care data sources covering more than 150 million European citizens. VAC4EU has implemented a research infrastructure including a cataloguing, a codemaker tool, a sharepoint, GitHub, digital research environment (DRE), a phenotype library of more than 100 variables with definitions and a Zenodo community to facilitate collaboration, transparency, and federated data analysis.

VAC4EU has adopted the ConoPON1 common data model as a basis for the structural harmonization of electronic health data, but it also allows for primary data collection. VAC4EU has consolidated its governance structure for implementation of pharmacovigilance studies on vaccines (figure 1) and successfully participated in four public tenders regarding vaccines safety and effectiveness launched by the European Medicines Agency (EMA) [1,2,3,4], as well as four required post-authorisation safety studies on COVID-19 vaccines sponsored by vaccine manufacturers [5,6,7,8], and other studies sponsored by the Global Vaccine Data Network [4]. All protocols developed within VAC4EU are registered in the EU PAS register, and results are published in the open science VAC4EU Zenodo community.

Conclusions

We know already from the H1N1 pandemic that collaboration is needed to study vaccine effects. This collaboration was designed and tested in the IMI-ADVANCE project and implemented in VAC4EU. VAC4EU has demonstrated readiness of its research framework making a key difference in COVID-19 vaccine monitoring in Europe. Research and public health organizations can join the initiative.

Declarations of interest

The authors and their department's conduct research for government, public, and private organizations, including pharmaceutical companies, according to the EUCOOP code of conduct.

References


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