International Alliance for
Biological Standardization

The Role of Real-World Evidence for Regulatory and Public Health Decision Making for Accelerated Vaccine Deployment

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Title: VAC4EU: experiences, lessons learned, remaining challenges

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The Vaccine Monitoring Collaboration for Europe was established as a non-for profit international association to generate best evidence about vaccines, post-marketing, in a collaborative manner. It was incorporated as legal entity in Belgium early 2020, just prior to the start of the Covid-19 pandemic. It is based on the blue print that was written by ECDC as part of the IMI-ADVANCE project.
Currently 31 research and public health organizations are a member. Vaccine manufacturers and publicly listed organizations cannot be a member of VAC4EU. VAC4EU members conduct studies on vaccines, using real world data. Data may be already collected (e.g. from electronic health records) or be collected de novo (e.g for cohort event monitoring). VAC4EU used principles of transparency and open science.
All protocols are listed on the EU PAS register, and project outputs (statistical analysis plans, code lists, scripts and reports) are posted on the zenodo public repositories in the VAC4EU community. VAC4EU conducts studies through a common protocol, a common data model (ConcePTION CDM), and common analytics, work groups define codelists, functions, algorithms and validation tools, which can be shared among members and publicly when finalized. Currently VAC4EU has supported four COVID-19 vaccine studies funded by EMA, and 6 studies requested by vaccine manufacturers as post authorization safety studies.