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

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Global Vaccine Data Network: experience, lessons learned, remaining
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Background: Following the initial detection of a possible relationship between receipt of ASO3 adjuvanted 2009 influenza vaccine and narcolepsy in Europe, multiple studies were conducted with different protocols yielding widely disparate results – some with a 16 fold increased risk and others with no increased risk. To try and address the need for globally coordinated studies with harmonized protocols, the Global Vaccine Data Network was established in 2019.

Current Status: In 2021 the US CDC funded the GVDN GCoVS project to evaluate the safety of COVID-19 vaccines and the network has grown to include more than 30 countries. Since that time, harmonized protocols have been developed to develop background rates, observed versus expected ratios, and to conduct association studies for Guillain-Barré Syndrome, myo-/peri-carditis, VITT, VMED and the safety of maternal immunization. The first two studies are complete whereas data collection is ongoing for the association studies.

Lessons Learned: The GVDN GCoVS study was funded one year after the start of the COVID pandemic. Without existing infrastructure, it was very time consuming to establish relationships, build trust and develop the protocols. While most protocols contemplated hands on medical record review, this has been difficult to achieve in a timely manner. Inclusion of low-income countries has required developing a separate data system.

Remaining Challenges: While the GVDN is successfully conducting investigator led global collaborative studies, the timelines for each project have been long. Work is in progress to develop a rapid response protocol to address new safety questions urgently. As always, availability of sustainable funding is an ongoing challenge.