



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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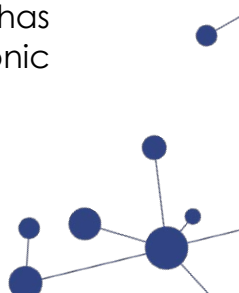
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Dr Julia Stowe has worked at UK Health Security Agency since 1999 on vaccine effectiveness and post-licensure epidemiological vaccine safety studies addressing pertinent vaccine safety concerns using routinely collected and electronic healthcare data. Routinely collected and electronic healthcare data is an indispensable tool for epidemiological research but especially in vaccine safety surveillance. These databases can never be used without the consideration of a great number of factors specific to the disease and vaccine. Her PhD assessed the methodological challenges in post-licensure vaccine safety studies and the epidemiological methods employed to quantify a risk, if any, of an adverse event after vaccination. These methods are employed to address the many sources of bias that are inherent when studying such complex conditions in a challenging setting.

Many of the epidemiological challenges are unique to vaccine safety surveillance due to a number of factors and methods employed in the surveillance of therapeutic drugs cannot be automatically transferred. These challenges and the need to be able to respond to vaccine safety concerns in a timely and methodological robust manner need to be balanced. Julia has expertise in the use, implementation and management of large electronic



datasets and has worked on many high-profile studies. She manages, designs, analyses and reports using these data carrying out epidemiological studies. She has also led the development of research proposals, writing scientific reports and papers for publication and presented epidemiological findings nationally and internationally at meetings and conferences.

