



International Alliance for
Biological Standardization



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

September 19-20, 2023
Park Inn Hotel, Leuven, Belgium

Title: The BeCOME project and its RWE roadmap

Philip Bryan (GSK), on behalf of the BeCOME Steering Committee.

Introduction

The COVID-19 pandemic brought about unique challenges for vaccines pharmacovigilance which required multistakeholder collaboration. Within the vaccine industry, several agile expert working groups were established during the pandemic to develop shared solutions to common topics. The BeCOME (Beyond COVID Monitoring Excellence) initiative arose from these unprecedented, non-competitive collaborations with the objective of building upon the positive gains in vaccine benefit-risk monitoring from the COVID experience and applying these to routine immunisations in a more sustainable way at a global level.

Challenges

The BeCOME initiative has identified several topics that would benefit from sustained collaboration to enhance vaccine benefit-risk monitoring. A multistakeholder workshop, including global regulators and non-government organisations, public health institutions, academia and industry was held in June 2023 to discuss the priority topics identified within BeCOME. The key topics discussed included innovation in signal detection (inc. safety data sources and digital tools), safety study conduct and pregnancy surveillance, vaccine benefit studies and enhancing vaccine pharmacovigilance in low and middle income countries (LMIC). The importance and value of multistakeholder collaboration and real-world evidence sits across these themes.

Proposed approach

Using input from the workshop, the BeCOME initiative will develop and publish a 5 year plan to tackle these priorities. Key to this will be the evolution of BeCOME from an industry collaboration to a multistakeholder, public-private partnership or collaboration.

Conclusions

The COVID 19 pandemic highlighted the need for, and value of, enhanced and sustained multistakeholder collaboration in future vaccine (and therapeutics) benefit-risk monitoring. The BeCOME initiative can serve as a platform to foster public-private relationships where there are common goals.