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Vaccines for pregnant women - challenges and opportunities for harmonized safety monitoring

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In the context of maternal immunization research which is globally expanding, the need to standardize definitions used for maternal and newborn conditions for monitoring potential adverse outcomes in pregnancy or the newborn that could occur in maternal immunization clinical trials is attracting much attention and effort. In July 2014, the World Health Organization hosted a conference along with the Brighton Collaboration to start the process of aligning terms of importance for maternal immunization with an emphasis on applicability in low to mid resource settings. This meeting identified priority terms for definition standardization. The Global Alignment of Immunization Safety Assessment in Pregnancy (GAIA)* project, funded by the Bill and Melinda Gates Foundation, is working to develop a core set of globally standardized case definitions of key outcomes, create case identification algorithms and data collection tools for monitoring immunization programs in pregnancy and develop guidance for harmonized data collection, analysis and presentation of these events. The first set of these priority definitions of interest to facilitate research and a common language in the field of maternal immunization have been developed by international working groups. Five neonatal and five obstetrics workgroups are in the process of reaching consensus definitions for the next set of ten terms. This presentation will discuss the challenges and opportunities for harmonized safety monitoring for Vaccines for Pregnant Women, key regulatory guidance and future needs. The GAIA project partners include Brighton Collaboration Foundation, WHO, NIH, Global Healthcare Consulting, University of Washington, Baylor College of Medicine, International Alliance for Biological Standardization, Monash Institute of Medical Research, Erasmus University Medical Center, Cincinnati Children's Hospital, St George's University of London, Public Health Agency of Canada and Synapse Research Management Partners, and are dedicated to promote and coordinate the work of over 200 volunteers in over 25 working groups.

Biography

Sonali Kochhar is a Physician and Clinical Researcher, MD, CEO and Medical Director of Global Healthcare Consulting. She has over nineteen years of leadership experience for Global Phase I-IV Clinical Research, Epidemiology and Safety Studies for Vaccines and Drugs for Infectious Diseases conducted in the USA, Europe, Asia, Africa and India in Adult and Pediatric populations. She has been responsible for leading international projects and teams in thirteen Asian, four African countries, Europe and USA. She is on various International Steering Committees, Scientific Advisory Boards and also serves as Guest Faculty for International Vaccinology Programs. She is a Reviewer for Vaccine, Lancet, Cochrane Review etc., and has published numerous international articles on vaccines.

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