

Research Project

VAESCO II Project

Third-party funded project

Project title VAESCO II Project

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Organisation / Research unit

Bereich Kinder- und Jugendheilkunde (Klinik) / Pädiatrie (Frey)

Department

Project start 01.07.2009

Probable end 30.06.2010

Status Completed

Goal: Availability of high quality and timely information on the safety of human vaccines based on a concerted effort of European member states. General Objectives: 1. To promote good practices /decision making in vaccine safety assessment. 2. To facilitate and accelerate the cooperation between the responsible agencies in Europe. 3. To build capacity within the field of disease prevention by providing tools and models founded on evidence based practice. 4. To support the improvement of human health through the delivery of safe and effective vaccines. Specific Objectives: 5. To foster close collaboration in a network of agencies responsible to collect and collate information on AEFI in Europe. 6. To evaluate and implement a self assessment tool of national and regional vaccine safety monitoring systems. 7. To conduct collaborative post-licensure epidemiologic studies, investigating AEFI reported to responsible agencies in European Member States by use of a guidance document for causality assessment. 8. To prepare for a European Vaccine Safety Data Link (EVSD) by determining the scope, identifying available resources, exploring opportunities for synergistic collaboration, and conducting proof of principle studies. 9. To assess the background rates of clinical outcomes in specified target populations of newly introduced immunization programs in anticipation of coincidences between immunization and these outcomes. Deliverables 1. Evaluation of the VAESCO Self-assessment tool for AEFI reporting systems EU Member States. 2. Update of the VAESCO Self-assessment tool based on the above evaluation 3. Collaborative pilot studies assessing the causal relation between a given immunization and a predefined AEFI in EU Member States based on the VAESCO guidance for causality assessment. 4. An network of existing and new national and regional large linked data bases (EVSD) encompassing immunization and clinical outcome data in several EU Member States 5. Proof of principle studies evaluating opportunities and challenges of concerted collection, sharing, analysis and presentation of vaccine safety data within and across EU member states. 6. Collaborative studies assessing the background rates of AEFI

Financed by

Foreign Governmental Research Agencies

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