



Partner Profile

The AEMPS is a public body which belongs to the Ministry of Health. Its main task is to regulate all aspects of human and veterinary medicines, from authorization to pharmacovigilance, so that marketed medicines have guarantees of efficacy, quality and safety. Regarding pharmacovigilance, the Agency has developed and currently maintains BIFAP, a General Practice database containing anonymised clinical records from 3.5 million patients and more than 15 million patient-years that has proved useful for pharmacoepidemiological research, including vaccines.

Website: www.aemps.es

Role in the ADVANCE Project

The Pharmacovigilance and Pharmacoepidemiology Unit of the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) participates in the WP3 and WP5 of ADVANCE project evaluating the characteristics of the primary care database BIFAP to investigate the use and risks associated to vaccines through the ADVANCE platform.

Key People

Dolores Montero. Head of Pharmacovigilance and Pharmacoepidemiology Unit of the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS). She is a member of the Pharmacovigilance Risk Assessment Committee (PRAC) at the European Medicines Agency. Her areas of expertise are in Signal detection and management, safety evaluation, benefit-risk monitoring, and risk management. She is co-director of BIFAP project.

Paco de Abajo. Professor of Pharmacology at the University of Alcalá and responsible of the Unit of Clinical Pharmacology at the University Hospital "Principe de Asturias". Scientific co-director of BIFAP contributing to methods development and POC studies.

Miguel Gil. Medical Doctor with a specialization degree in Preventive Medicine and Master in Public Health. He is coordinator and epidemiologist of BIFAP project. He has experience in pharmacoepidemiological designs and methods.

Consuelo Huerta. Medical Doctor, Master in Public Health. She is Pharmacoepidemiologist at the Spanish Agency for Medicines and Medical Devices, AEMPS and in BIFAP Database. She has

experience in pharmacoepidemiological designs and methods, and in pharmacovigilance of pandemic vaccines, Flu A (H1N1).

Elisa Martín. Elisa Martin-Merino is a Pharm, PhD. Fellow of Department of Epidemiology in the Harvard School of Public Health in 2011 with an Award of the Real Colegio Complutense in Harvard. PhD in the Department of Preventive Medicine of the Complutense University of Madrid (2011) assessing the risk of acute coronary syndrome associated to non-steroidal anti-inflammatory drugs. Master in Science in the Department of Public Health and Microbiology of Salamanca University with a study assessing the prevalence of hepatitis B and C and HIV in a correctional facility

JoséLuis Alonso-Lebrero. Pharmacy Degree, Biology PhD and Master in Business Administration. He is the Agency project manager in all research European projects. He has experience in managing research projects in the Health area.

Cesar de la Fuente. Pharmacy Degree, specialist in Hospital Pharmacy. Since 2008 he is head of the Pharmacoepidemiology Service of the Pharmacoepidemiology and Pharmacovigilance Unit (AEMPS). His areas of expertise are assessment of protocols of non-interventional post-authorization studies, and drug utilization research (including BIFAP as data source).
