Training on pharmacovigilance (vaccines)
25 January to 3 February 2022

Online

Agenda

The training program is aiming to enhance capacities of low- and middle-income countries on COVID-19 vaccine safety and effectiveness as part of their efforts to implement their national vaccination programs for COVID-19 vaccines.

1.1 Day 1 (Tuesday, 25 January 2022)

Session moderator: Adriana Bastidas (P95)/ Gabriela Cuenca (ARCSA)

Time (CET)	Topic	Main facilitator
2:00 PM - 2:30 PM CET	Welcome and Introduction of ARCSA	José Intriago
	Welcome words and short presentation of GIZ	Danny Denolf
	Welcome words and short presentation of P95	Thomas Verstraeten
	Overview of pharmacovigilance/ vaccinovigilance in Ecuador	Margarita Galarza
2:30 PM - 2:35 PM CET	Summary of pre-course Quiz results	Wendy Hartig-Merkel
2:35 PM to 2:40 PM CET	Overview of the training course and presentation of objectives	Philip Bryan
2:40 PM - 3:30 PM CET	**Module 1: An introduction to pharmacovigilance and vaccine safety**	Philip Bryan
3:30 PM - 3:45 PM CET	*Coffee/ Tea break*	
3:45 PM - 4:15 PM CET	**Module 1 - Questions & Answers session (Spanish)**	Adriana Bastidas (P95)
4:15 PM - 4:20 PM CET	Wrap up, end of Day 1	Adriana Bastidas (P95)

1.2 Day 2 (Wednesday, 26 January 2022):

Session moderator: Margarita Riera (P95)/ Gabriela Cuenca (ARCSA)

Time (CET)	Topic	Main facilitator
2:00 PM - 2:05 PM CET	Welcome Day 2	Margarita Riera (P95)
2:05 PM - 2:50 PM CET	**Module 2: Overview of regulatory requirements in Pharmacovigilance**	Claire Behm
2:50 PM - 3:10 PM CET	**Module - Q&A session** (Spanish)	Margarita Riera (P95)
3:10 PM - 3:20 PM CET	*Coffee/ Tea break*	
3:20 PM - 4:00 PM	**Module 3: Data collection – Clinical safety and passive pharmacovigilance**	Elodie Solé
4:00 PM - 4:20 PM	**Module 3 - Q&A session** (Spanish)	Margarita Riera (P95)
4:20 PM - 4:25 PM CET	Wrap-up, End of Day 2	Margarita Riera (P95)

1.3 Day 3 (Thursday, 27 January 2022):

Session moderator: Elvira Carrió (P95)/ Gabriela Cuenca (ARCSA)

Time (CET)	Topic	Main facilitator
2:00 PM - 2:05 PM CET	Welcome Day 3	Elvira Carrió (P95)
2:10 PM - 3:15 PM CET	**Module 4: Signal detection and risk assessment**	Philip Bryan
3:15 PM - 3:25 PM CET	*Coffee/ Tea break*	
3:25 PM – 3:55 PM CET	**Module 4 - Q&A session** (Spanish)	Elvira Carrió (P95)
3:55 PM - 4:00 PM CET	Wrap-up, End of Day 3	Elvira Carrió (P95)

1.4 Day 4 (Tuesday, 1 February 2022):

Session moderator: Belen Machado (P95)/ Gabriela Cuenca (ARCSA)

Time (CET)	Topic	Main facilitator
2 PM to 2:05 PM CET	Welcome Day 4	Belen Machado (P95)
2:05 PM to 3:20 PM CET	**Module 5 – Proactive surveillance and Risk Management Planning**	Philip Bryan
3:20 PM to 3:30 PM CET	*Coffee/ Tea break*	
3:30 PM to 3:50 PM CET	**Module 5 - Q&A session (in Spanish)**	Belen Machado (P95)
3:50 PM to 3:55 PM CET	Wrap up, End of Day 4	Belen Machado (P95)

1.5 Day 5 (Wednesday, 2 February 2022):

Session moderator: Elodie Solé (P95)/ Gabriela Cuenca (ARCSA)

Time (CET)	Topic	Main facilitator
2 PM to 2:05 PM CET	Welcome Day 5	Elodie Solé (P95)
2:05 PM to 3:10 PM CET	**Module 6 (Part 1) – PASS for vaccines, Vaccine effectiveness, impact studies and Benefit-Risk assessment (post-authorisation)**	Kaat Bollaerts
3:10 PM to 3:20 PM CET	*Coffee/ Tea break*	
3:20 PM to 3:55 PM CET	**Module 6 (Part 2) – PASS for vaccines, Vaccine effectiveness, impact studies and Benefit-Risk assessment (post-authorisation)**	Kaat Bollaerts/ Philip Bryan
3:55 PM to 4 PM CET	Wrap up (Q&A for this sessions will be part of the exercise tomorrow) , End of Day 5	Elodie Solé (P95)

1.6 Day 6 (Thursday, 3 February 2022):

Session moderator: Zuleika Aponte (P95)/ Gabriela Cuenca (ARCSA)

Time (CET)	Topic	Main facilitator
2 PM to 2:05 PM CET	Welcome Day 6	Zuleika Aponte (P95)
2:05 PM to 3:40 PM CET	**Practical exercise - Signal detection and risk assessment, PASS, VE study, and balancing benefits against a putative risk (inc. Q&A)**	Kaat Bollaerts/ Philip Bryan/ Zuleika Aponte (P95)
3:40 PM to 4 PM CET	**Quiz** to assess knowledge on vaccine safety and effectiveness after the training	Wendy Hartig-Merkel
4 PM to 4:15 PM CET	Feedback from participants	Zuleika Aponte (P95)/ Gabriela Cuenca (ARCSA)
4:15 PM to 4:30 PM CET	Closure words and next steps	GIZ
	Closure words of P95	Philip Bryan and Thomas Verstraeten
	Closure words of ARCSA	José Intriago Margarita Galarza
End of workshop		

About P95

P95 is a for-profit SME serving a global clientele through excellence in science. P95 was founded by Thomas Verstraeten in June 2011.

Our focus is on finding new solutions for complex health problems and we address our clients' needs with a sense of urgency. P95's main area of expertise is vaccine related epidemiology, pharmaco-epidemiology and pharmacovigilance. We care about public health and how we can contribute to it.

Our clients are non-profit organizations such as the World Health Organization (WHO), Coalition for Epidemic Preparedness Innovations (CEPI) and the Bill and Melinda Gates Foundation as well as many pharmaceutical companies, to whom we provide support throughout all clinical development and post- marketing stages of their pharmaceutical products. In addition, P95 is a partner in several European Union (EU) Innovative Medicines Initiative projects ADVANCE (Accelerated Development of VAccine beNefit-risk Collaboration in Europe), DRIVE (Development of Robust and Innovative Influenza Vaccine Effectiveness) and VITAL (Vaccines and infectious diseases in the ageing population) and provides scientific and administrative support to the European Commission Scientific Panel for Health. Through engagement and collaboration with academics, private companies, and the public sector, we innovate in health research across Europe and beyond.

Since the COVID-19 pandemic began, P95 has been supporting several pharmaceutical companies in the development of COVID-19 vaccines: assessment of safety data from clinical trials, options for post-marketing pharmacovigilance activities, safety and effectiveness studies, and risk minimisation strategies. P95 is proud to be part of the global effort to fight COVID-19.

Learn more about us: https://www.p-95.com/

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About the trainers and the moderators

Zuleika Aponte-Torres is an epidemiologist with experience in the fields of safety epidemiology and infectious diseases. Zuleika has a degree in Biology and a master's degree in Public Health and Epidemiology from the University of Puerto Rico. For the past two years she worked as a consultant epidemiologist for both the private and public sectors. Previously, she worked as the epidemiologist team lead at the National Healthcare and Safety Network providing epidemiology strategies to medical facilities, state, and national health agencies on infection surveillance and prevention at the Centers for Disease and Control (CDC). She also worked as the safety epidemiologist for Novartis and Pfizer in Barcelona, Spain supporting epidemiological research studies in infectious diseases and oncology. Her research work in different organizations has led to several publications in the field of respiratory diseases, infectious disease, oncology, and rare diseases epidemiology. She joined P95 as an epidemiologist in February 2021.

Adriana Bastidas graduated as a Medical Doctor at Universidad Católica de Santiago de Guayaquil in 1998 and specialized in Oncology.
She worked at the Catholic University Leuven understanding gene expression in aggressive fibromatosis and mechanisms of tumor cell implantation.
Afterwards she worked at GSK Vaccines for 11+ years. During this time, she gained experience in post-marketing surveillance and safety development of flu seasonal and quadrivalent vaccines (3 years), and later moved to the clinical development program of the zoster vaccine where she actively worked and oversaw the development of the vaccine until it's marketing authorization in US and EU (8+ years). Before joining P95, she worked at Mithra Pharmaceuticals for 2 years where she headed the clinical development and medical affairs department and guided the teams through the marketing authorization of a new class of estrogen in US, EU, and Australia.
Adriana joined P95 in May 2021 to expand P95 activities in Latin America and establish P95 Latina in 2021.

Claire Behm trained as a Public Health Physician in Australia and holds Bachelor degrees with Honours in Medicine/Surgery and Biotechnology, a Masters of Public Health, a Graduate Certificate in Drug Development and Fellowship of the Australasian Faculty of Public Health Medicine. Prior to moving to the United Kingdom, Claire worked as a Principal Medical Advisor in the Pharmacovigilance and Special Access Branch at the Therapeutic Goods Administration in Australia, where she led a team responsible for the post-market surveillance of medicines and vaccines. Claire joined P95 as a Safety Physician in November 2021.

Kaat Bollaerts is a statistician with a passion for epidemiology. She holds Masters in Psychometrics (2001), Teaching (2002) and Statistics (2004). In 2009, she obtained her PhD in Statistics with a thesis topic on epidemiology. Before joining P95 in 2013, she worked for 4 years at Public Health Belgium.

Philip Bryan graduated from the University of Sheffield with a BSc in Pharmacology and Physiology in 1994, after which he gained a PhD in physiology from the University of Birmingham (UK) in 1998 and a certificate in Pharmacovigilance and Pharmacoepidemiology at the London School of Hygiene and Tropical Medicine in 2000. From 1998 to 2021 Phil worked at the UK Medicines and Healthcare Products Regulatory Agency, where he led on vaccine pharmacovigilance. Phil also worked very closely with public health authorities across the UK and the national immunisation advisory committees and, most recently, oversaw the vigilance strategy for COVID-19 vaccines.

Elvira Carrió is a scientist and medical writer with international experience in the fields of Infectious Diseases and Gene Regulation. Elvira holds a BSc in Biology, an MSc in Developmental Biology and Genetics, a Ph.D. in Genetics from the University of Barcelona (Spain) and a Postgraduate on Global Health Care and Management: From Research to Implementation, from the TropEd network and the University of Basel (Switzerland). Her Ph.D. addressed the epigenetic and genetic regulation of muscle stem cells and included a stay at the Cancer and Cardiovascular Research Unit at the University of Minnesota (USA). She later worked at the Germans Trias Health Research Institute in Badalona (Spain), assessing the impact of bariatric surgery on epigenetic regulation. During her postdoc at the Swiss TPH, she applied her background to the infectious disease field and researched the genetic triggers of malaria parasite transmission. Elvira joined P95 as a medical writer in April 2020.

Wendy Hartig-Merkel holds the degrees Doctor of Veterinary Medicine (2003) and PhD in Herd and Population oriented Research (veterinary medicine; 2014) from the University of Copenhagen (Denmark). In her PhD, she examined the scientific background for the establishment of a national health database. After her PhD, she worked within research and development, regulatory affairs, and pharmacovigilance within the veterinary sector and joined P95 as a medical writer in May 2020.

Belen Machado is a Medical Doctor, has an academic background in clinical Epidemiology at university foundation of Health sciences, her experience as a doctor started with a medical internship in which she worked with indigenous people in the south of Colombia, in the department of Nariño. Later she gained experience in hospitals of high levels of complexity in the city of Bogotá, conveniently using the principles of evidence-based medicine. Currently she is a resident of clinical pharmacology of Sabana University. She joined P95 in May 2021 as Epidemiologist.

Margarita Riera graduated as MD from the Universidad de Barcelona in 1998. After specializing in Internal Medicine, she pursued an MSc in Tropical Medicine and International Health at the London School of Hygiene and Tropical Medicine. She went on to work in medical emergency relief in Asia and Africa and then joined the European Program for Intervention Epidemiology Training (EPIET) at the European Centre for Disease Prevention and Control (ECDC), after which she worked for Epicentre research bases in Niger and Uganda. She joined P95 as epidemiologist in 2013 and currently serves as the Chief Operating Officer.

Elodie Solé graduated as pharmacist specializing in hospital pharmacy in 2012 and completed this academic background with a Master of Pharmacoepidemiology and Pharmacovigilance.
The following five years Elodie worked for a National Competent Authority as pharmacovigilance assessor. She was involved in the assessment of post-marketing and clinical trials safety data in different therapeutic areas. She joined P95 as safety scientist in 2018.

Thomas Verstraeten graduated as MD from Ghent University in 1987 and obtained a degree in Tropical Medicine from the Institute of Tropical Medicine in Antwerp in 1988. After about 10 years working in the field in emergency relief in Africa and HIV/STD research and surveillance and obtaining a Masters in biostatistics from the University of Limburg, he was selected for a 2-year fellowship as Epidemiology Intelligence Service officer at the Centers for Disease Control within the Vaccine Safety Branch. After completing the fellowship, he joined GSK for 10 years where he first led the vaccine epidemiology group, later leading the vaccine safety group and finally in charge of the Health Outcomes Group. After leaving GSK, he founded P95 in 2011 and is the current Chief Executive Officer.