Curriculum Vitae

Personal information

Francesco Trotta

Work experience

1. Employer: AIFA
   - Start date: 092020
   - End date: 072021
   - Position: Scientific Manager (Pharmacist)
   - Activities: Secretariat of the Director General (ad interim)
   - Country: Italy
2. Employer: AIFA
   - Start date: 062020
   - End date:
   - Position: Scientific Manager (Pharmacist)
   - Activities: HTA Division, Head
   - Country: Italy
3. Employer: Italian Medicnes Agency (AIFA)
   - Start date: 092017
   - End date:
   - Position: Scientific Manager (Pharmacist)
   - Activities: Monitoring of drug consumption and expenditure, Head of Office
   - Country: Italy
4. Employer: Department of Epidemiology, Lazio Region
   - Start date: 062015
   - End date: 092017
   - Position: Pharmacoepidemiologist (on secondment from AIFA)
   - Activities: Conduction of pharmacoepidemiology studies and of health technology assessment evaluations. Member of the scientific secretariat of the Committee for Drug Evaluation of the Lazio Region; Member of the Pharmacovigilance Committee of the Lazio Region. Member of the Regional Group for the Signal Evaluation on Drugs (GLASS). Member of the Biosimilar Working Group of the Lazio Region.
   - Country: Italy
5. Employer: Italian Medicnes Agency (AIFA)
   - Start date: 012009
   - End date: 092017
   - Position: Scientific administrator, Pharmacovigilance Unit
   - Activities: Member of the committee for active pharmacovigilance programme aimed at funding both regional and national pharmacovigilance studies/projects (budget: approx. 25 million euro/year); Management and coordination of the programme; follow up of the project funded, auditing activity; networking; dissemination of the programme and related results. More than 150 regional and national projects have been funded since 2007. A report on the funded project has been issued in 2013 (see publication section). · Evaluation of the activities of Regional Pharmacovigilance Centres; set up guidelines and indicators; conduction of audits; evaluation and dissemination of results. ·Participation and coordination activity on observational study/surveillance investigating safety and effectiveness issues: i) Safety and effectiveness evaluation of the medicines and vaccines in children; ii) Association between seasonal flu vaccination and GBS; iii) co_investigator of VAESCO PIV Narcolepsy: study on the background rates of narcolepsy and the association between H1N1 vaccination and narcolepsy). · Assessment of the Risk Management Plan (pre_ and post_authorization) and Risk Management System of medicinal products submitted via centralized or mutual recognition/decentralized and national procedures; · Assessment of clinical safety dossiers, PSURs, and other post_marketing studies (e.g. observational studies, Trials, DUS); · Assessment of renewal applications' dossiers; · Signal detection and management (both at national and international level); · Member of the working group of vaccinovigilance. An annual report on the vaccine surveillance in Italy has been published since 2010 (see publication section).·Risk management and risk communication of emerging safety issues; ·Evaluation of spontaneous reports registered within the National PhV database;· Specific areas of expertise: Vaccines, Oncology, Respiratory drugs; Genito_urinary drugs, hormones.
   - Country: Italy
6. Employer: Researcher in Pharmacoepidemiology
   - Start date: 012013
   - End date: 122013
   - Position: Italian National Institute of Health
   - Activities: Conduction of pharmacoepidemiology studies. Responsible for all the study phases reported below: · the selection of the most appropriate methodological strategies to answer research questions, both on issues of safety and efficacy, related to drugs and vaccines; · Writing of the research protocol, including the rationale, methodology and analysis plan provided; · organization of the conduct of the study, including the stages of collection and verification of data quality; · data analysis including both the preparation of the database for the analysis that the execution of the plan for statistical analysis; · interpretation of results and writing of the final report, including the publication of results in scientific journals. The following projects and activities are part of the research plan: · an etiological study (based on record_linkage amongst different databases) to investigate the association between pandemic influenza vaccination in pregnant women pregnancy and pregnancy and neonatal outcomes. · a drug utilization study to investigate the impact of switch among generic medicines on treatment adherence; · an incidence study aimed at evaluating the background of incidence of an event possibly occurring after the administration of vaccines (e.g. the intussusceptions);

- Country: Italy

7. Employer: Italian Medicines Agency (AIFA)
   - Start date: 062007
   - End date: 052009
   - Position: Scientific administrator, R&D Unit
   - Activities: Contributing to the assessment and revision of the letters of intent and clinical protocols funded by the AIFA's independent research program on drugs (particularly for studies referred to orphan drugs, rare diseases, and oncology field). An approximate budget of 20 million euro per year was allocated to the research program. More than 200 independent studies were funded. A report on the funded project has been issued in 2008 and a original article has been published in a peer reviewed journal (see publication section). · Clinical and scientific monitoring of the funded studies. · Member of the scientific secretariat of the AIFA's R&D Committee. · Scientific support to the preparation and management of the annual AIFA's call for proposals. · Scientific advice to the researchers in the submission of letters of intents and full study protocols. · Member of the scientific secretariat during the Study session in which the full study protocols are assessed. · Advice to the researchers during the conduction of the studies; · Follow up/Auditing of funded studies
   - Country: Italy
8. Employer: Italian National Institute of Health
   - Start date: 092006
   - End date: 062007
   - Position: Research Fellow, Expert of European Assessment Procedures
   - Activities: Assessment of drug dossiers accompanying marketing authorisation applications following mutual recognition, decentralised and centralized procedures, and preparing assessment reports according to the standard required by the European Medicines Agency. · Assessment and revision of the Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL) and Labelling of drugs approved by mutual recognition and decentralised procedures both for new marketing authorisations or for type I and II variations or renewals.
   - Country: Italy

Education and training

1. Subject: National School of Management, The Presidency of the Council of Ministers – Government of the Italian Republic, Rome
   - Start date: 092017
   - End date: 122017
   - Qualification: XXVI national training course for public managers
   - Organisation: • Public administration • Accounting, Law, Economics • Organization and People Management • Innovation and Strategy
   - Country: Italy
2. Subject: London School of Hygiene & Tropical Medicine
   - Start date: 112011
   - End date: 072012
   - Qualification: Certificate in Pharmacoepidemiology and Pharmacovigilance
   - Organisation: · epidemiology; · statistics; · pharmacoepidemiology; · historical and legal background to pharmacovigilance and pharmacoepidemiology; · pharmacological basis of ADEs; · addressing ADE issues at individual and population levels; · application of pharmacoepidemiological principles and methods to practical drug issues
   - Country: United Kingdom
3. Subject: London School of Hygiene & Tropical Medicine
   - Start date: 092010
   - End date: 102010
   - Qualification: Short course in Epidemiological evaluation of vaccines: efficacy, safety and policy.
   - Organisation: Epidemiological principles of vaccine evaluation · Immunological basis for vaccination · Pre_licensure epidemiological issues (Phase I, II and III trials, Practical and ethical considerations, Clinical trials: sample size and analysis issues, Good clinical practice and adverse event monitoring during vaccine trials) · Post_licensure epidemiological issues (Vaccine efficacy and effectiveness, Impact studies, Burden of disease assessment, Surveillance of disease and infection, Adverse events monitoring) · Using immunology in vaccine evaluation · Infectious disease modelling in assessing vaccine impact · Economic evaluation of vaccination programmes · Key issues in vaccination schedules and policy · Long term implications of vaccination programmes · Topical issues in the epidemiology of vaccine preventable disease
   - Country: United Kingdom
4. Subject: Faculty of Medicine, Department of Public Health, University of Rome "La Sapienza
   - Start date: 012007
   - End date: 022010
   - Qualification: Specialization School in Health Statistics and Epidemiology
   - Organisation: Medical statistics; epidemiology, Health technology assessment; pharmacoeconomics, health planning; meta_analysis, guidelines and appropriateness of interventions; surveillance; pharmacoepidemiology; automated data_analysis techniques (training in SPSS software); screening programs evaluation; clinical methodology. · The thesis has been prepared at Department of Pharmacoepidemiology of the Italian National Health Institute (ISS) and concerned the investigation of the relationships between the outcomes and the appropriateness of pharmacological treatment administered as secondary prevention after an episode of acute myocardial infarction.
   - Country: Italy
5. Subject: Institute for Pharmacological Research "Mario Negri" (IRFMN), Milan and Italian Medicines Agency (AIFA), Ministry of Health, Rome
   - Start date: 012005
   - End date: 082006
   - Qualification: Drug Evaluation School (DESch)
   - Organisation: Expert support to the Rapporteurship/Co_Rapporteurship for new marketing authorisation applications and for a number of post_marketing commitments, and variations and renewals of the marketing authorisations. · Assessment of drug dossiers accompanying marketing authorisation applications in terms of quality, safety and efficacy, and preparing assessment reports according to the standard required by the European Medicines Agency. · Evaluation of the appropriateness of drug legislation and regulatory procedures with respect to public health needs. · Evaluation of suitability of standards for the planning and the conduction of clinical trials in the principal clinical areas (clinical methodology).
   - Country: Italy
6. Subject: Department of Experimental Pharmacology, University of Naples "Federico II"
   - Start date: 012002
   - End date: 072002
   - Qualification: Perfection course in medicinal plants and natural products pharmacology.
   - Organisation:

- Country: Italy

7. Subject: Faculty of Pharmacy, University of Siena
   - Start date: 092001
   - End date: 122004
   - Qualification: Ph.D in Pharmaceutical Sciences
   - Organisation: Development of the lead_compound: experience in the improvement and characterization of the pharmacodynamic (SAR, QSAR, intrinsic activity) and pharmacokinetic (ADME_Tox) properties of the compound; · Design, evaluation and assessment of in vitro and in vivo tests for compounds potentially active on CNS (antipsychotics, antiepileptics, antidepressive drugs, drugs for neurodegenerative disease, drug abuse treatments); · Development of organic and bioinorganic synthesis methods (heterocyclic chemistry, unnatural amino acids); · Good knowledge of solid phase combinatorial synthesis methods for small libraries of heterocyclic compounds. · Good knowledge of principal extraction, separation and purification techniques. · Good knowledge of analytical methods (NMR, GC/MS, LC/MS, HPLC, IR and UV_Spectroscopy, Polarimetry). · Teaching and laboratory assistant (laboratory student's medicinal chemistry courses) of the Faculty of Pharmacy · Laboratory teaching activity for the students.
   - Country: Italy
8. Subject: Faculty of Pharmacy, University of Siena
   - Start date: 011995
   - End date: 122001
   - Qualification: Degree in Pharmacy
   - Organisation: Title of the thesis: "Synthesis and Pharmacological Evaluation of Novel Pyrrolo[2,1_b][1,3]benzothiazepine (PBT) as Potential Atypical Antipsychotic Activity". Score: 110/110 (cum laude)
   - Country: Italy

Additional information

Publications

Co_author of more than 100 articles published in national and international scientific journals

Projects

Memberships

Other Relevant Information