Curriculum Vitae

Personal information

Barbara Kovacic Bytyqi

Work experience

Employer: Croatian Agency for Medicinal Product and Medical Devices

- Start date: 11 2023/2 2024
- End date:
- Position: Head of Pharmacovigilance and Rational Pharmacotherapy Department/PRAC Alternate

Employer: Croatian Agency for Medicinal Product and Medical Devices

- Start date: 012018
- End date: 10 2023
- Position: Pharmacovigilance Assessor
- Activities:

- PSUR assessment

- RMP assessment

- signal detection

- assessment of safety variations

- Country: Croatia

Employer: Ministry of Health

- Start date: 042017
- End date: 012018
- Position: Associate
- Activities:

Worked in Service for blood, tissue and cell inspection on administrative assignments such as preparing and reviewing documentation before and after inspections.

- Country: Croatia

Education and training

1. Subject: Department of Clinical Epidemiology at Aarhus University and Aarhus University Hospital
   - Start date: 062022
   - End date: 062022
   - Qualification: Pharmacoepidemiology Summer School 2022
   - Organisation: Drugs, Diseases, Designs: Topics and methods in real_world pharmacoepidemiology. Epidemiologic study design, prescription data and sources of bias in pharmacoepidemiology. Confounding by indication, healthy user effects. Studying comparative effectiveness and drug safety. Treatment patterns and recurrence, immortal time bias, targeted therapies. Longitudinal data, defining outcomes using laboratory values, longitudinal data with repeated measurements. Design, analysis, and bias as applied to studies of drug treatment in pregnancy. Drug utilization and risk minimization studies. Interrupted time series regression. Meta_analysis.
   - Country: Denmark
2. Subject: EMA
   - Start date: 122021
   - End date: 122021
   - Qualification: PhV assessments – challenges and solutions for PhV assessors (webinar)
   - Organisation: Objectives of the training: To enhance the understanding of: • evaluation of risk minimisation measure (RMM) effectiveness and pharmacovigilance impact research in line with GVP module XVI on 'Risk minimisation measures: selection of tools and effectiveness indicators' (Rev.3), based on study examples; key principles, qualitative and quantitative objectives of RMM effectiveness evaluation and impact research; • overview of key methodologies and analytical approaches for impact research; methodological issues based on past_experience with MAH_sponsored studies and EMA commissioned impact research; • safety monitoring tools for medicinal products indicated for the prevention and treatment of SARS_Cov_2 infection / COVID_19; • data analysis tool of real_world data (RWD) to support PRAC procedures and their scientific and regulatory outcomes; • best practice for periodic safety update report single assessment (PSUSA) procedures to handle confidential information (commercially confidential information and personal data).
   - Country: Netherlands
3. Subject: Elevate Academy
   - Start date: 092021
   - End date: 092021

- Qualification: Pharmacoepidemiology and Drug Safety
- Organisation: Cohort and case_control study designs Confounding and other biases – introduction/new approaches Critical appraisal of publications Overview and application of pharmacoepidemiologic databases The future of electronic health record database research The value of individual patient observations in drug safety research Continuous evaluation of harm/benefit Molecular pharmacoepidemiology
- Country: Netherlands

4. Subject: EMA
   - Start date: 112020
   - End date: 112020
   - Qualification: PhV assessments – challenges and solutions for PhV assessors (webinar)
   - Organisation: Objectives of the training: To enhance the understanding of: • appropriate ways of authorising, risk management planning and safety surveillance of vaccines. • pharmacovigilance of vaccines to prevent SARS_CoV_2 infection / COVID_19 during a pandemic, including vaccines using novel technologies (e.g. mRNA). • issues related to the rolling review, authorisation and safety surveillance of medicinal products intended for the prevention and treatment of SARS_Cov_2 infection / COVID_19. • issues relating to the additional monitoring status, best practice for periodic safety update report (PSUR) single assessment (PSUSA) assessment reports and use of rapid data analysis for regulatory decisions.
   - Country: Netherlands
5. Subject: EMA
   - Start date: 112019
   - End date: 112019
   - Qualification: PhV assessments – challenges and solutions for PhV assessors
   - Organisation: Objectives of the training: • To understand issues related to the safe use of medicines during pregnancy and lactation and their assessment and implementing appropriate risk minimisation measures. • To improve the understanding of appropriate ways of gathering reliable evidence to further characterise and quantify risks of medicinal products via post_authorisation safety studies (PASS) including registry_based studies. • To gain a better understanding of issues relating to the safety of advanced therapy medicinal products (ATMPs), their risk management and further investigation of long_term risks. • To improve the detection and assessment of cases of drug_induced liver injury (DILI) through assessors' guidance and its practical applicability through case studies.
   - Country: Netherlands
6. Subject: The Maintenance and Support Services Organization (MSSO)
   - Start date: 032019
   - End date: 032019
   - Qualification: MedDRA: Data Analysis and SMQs
   - Organisation:
   - Country: Serbia
7. Subject: The Maintenance and Support Services Organization (MSSO)
   - Start date: 032019
   - End date: 032019
   - Qualification: Coding with MedDRA
   - Organisation:
   - Country: Serbia
8. Subject: COST/University of Malaga
   - Start date: 032019
   - End date: 032019
   - Qualification: 1st Training Course COST Action 17_112 PRO_EURO DILI NET
   - Organisation:
   - Country: Spain
9. Subject: CBG MEB
   - Start date: 012019
   - End date: 012019
   - Qualification: ICP Pharmacovigilance training
   - Organisation:
   - Country: Netherlands
10. Subject: EMA
    - Start date: 112018
    - End date: 112018
    - Qualification: PhV assessments – challenges and solutions for PhV assessors (webinar)
    - Organisation:
    - Country: United Kingdom
11. Subject: Atrium
    - Start date: 102018
    - End date: 102018
    - Qualification: Pharmacovigilance workshop in Zagreb
    - Organisation:
    - Country: Denmark
12. Subject: EMA
    - Start date: 062018
    - End date: 062018
    - Qualification: Webinar _ 2018 Pharmacovigilance Training
    - Organisation:
    - Country: United Kingdom
13. Subject: European Medicines Agency (EMA)
    - Start date: 052018
    - End date: 052018
    - Qualification: EVDAS Training for National Competent Authorities
    - Organisation:
    - Country: United Kingdom
14. Subject: University of Rijeka: Department of Biotechnology
    - Start date: 102014
    - End date: 112016
    - Qualification: Master of Biotechnology in Medicine
    - Organisation:
    - Country: Croatia
15. Subject: University of Rijeka: Department of Biotechnology
    - Start date: 102011
    - End date: 092014
    - Qualification: Bachelor of Biotechnology and Drug Research
    - Organisation:
    - Country: Croatia

Additional information