



## Curriculum Vitae

Personal information **José Javier Sawchik Monegal**

### Work experience

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1. Employer: Federal Agency for Medicines and Health Products
  - Start date: 062013
  - End date:
  - Position: Assessor (POST \_ Biostatistics/Pharmacoepidemiology)
  - Activities: Evaluation of protocols, SAP, and study reports for PASS and other epidemiological studies. Support for signal evaluation. Basic training on biostatistics and pharmacoepidemiology for pharmacovigilance assessors. Applications and Clinical Trial Applications. Protocol development, data management and analysis, and writing of study reports of surveys conducted for assessing effectiveness of risk minimization measures and drug utilization..
  - Country: Belgium
2. Employer: Federal Agency for Medicines and Health Products
  - Start date: 032011
  - End date: 052013
  - Position: Assessor in Biostatistics (PRE)
  - Activities: Evaluation of methodological sections and results in Marketing Authorization Applications and Clinical Trial Applications. Scientific advice on protocols for clinical trials. Basic training on biostatistics for clinical assessors.
  - Country: Belgium
3. Employer: GSK Biologicals
  - Start date: 052008
  - End date: 022011
  - Position: Biostatistician
  - Activities: Contribution in protocol development. Sample size calculations. Writing of Statistical Analysis Plan and statistical report. Review of Clinical Study Report. Statistical analysis, SAS programming and QC. Review of manuscripts. Review of SOPs. Review of cleaning plan and Case Report Form.
  - Country: Belgium
4. Employer: Citibank
  - Start date: 052007
  - End date: 042008
  - Position: Database officer
  - Activities: Data mining. Sas programming.
  - Country: Belgium
5. Employer: UCB
  - Start date: 072005
  - End date: 042007
  - Position: Biostatistician
  - Activities: Contribution in protocol development. Sample size calculations. Writing of Statistical Analysis Plan. Review of Clinical Study Report. Statistical analysis, SAS programming and QC. Review of cleaning plan and Case Report Form.
  - Country: Belgium
6. Employer: UCB
  - Start date: 022005
  - End date: 052005
  - Position: Internship (Outcomes research)
  - Activities: Data analysis. SAS programming. Review of literature.
  - Country: Belgium
7. Employer: Universidad de la Republica
  - Start date: 121989
  - End date: 012003
  - Position: Research associate
  - Activities: Research, teaching, data analysis, and project management in Ecology/Population Biology.
  - Country: Uruguay

### Education and training

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1. Subject: Université Catholique de Louvain
  - Start date: 2003
  - End date: 2005
  - Qualification: Master in Statistics
  - Organisation: Biostatistics, Pharmacoepidemiology.
  - Country: Belgium
2. Subject: Université Catholique de Louvain
  - Start date: 1995
  - End date: 1999
  - Qualification: PhD in Applied natural Sciences
  - Organisation: Ecology, Population biology, Biostatistics.
  - Country: Belgium
3. Subject: Universidad de la Republica

- Start date: 1991
  - End date: 1993
  - Qualification: Master in Biological Sciences (Ecology)
  - Organisation: Ecology, Biostatistics, Population Biology, Population Genetics.
  - Country: Uruguay
4. Subject: Universidad de la Republica
- Start date: 1985
  - End date: 1989
  - Qualification: BsC in Biological Sciences
  - Organisation: Biology, Biostatistics, Ecology.
  - Country: Uruguay

## Additional information

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### Publications

Skrinska-Kirilova V, Sawchik J, Sabbe M, Debacker M, Weber G, Vuillemin AC, Hamdani J, 2025. Evaluation of Awareness of Photosensitivity Risk and Additional Risk Minimisation Measures for Ketoprofen Gel in Belgium and Luxembourg. *Drugs Real World Outcomes*;12(3):425-435.

Sabbe M, Sawchik J, Gräfe M, Guillaume F, De Bruyn S, Van Antwerpen P, Van Hal G, Desseilles M, Hamdani J, Malonne H, 2022. Use and misuse of prescription stimulants by university students: a cross-sectional survey in the french-speaking community of Belgium, 2018. *Arch Public Health*16;80(1):54.doi: 10.1186/s13690\_022\_00816\_3.

Sawchik J, Hamdani, Vanhaeverbeek M, 2018. Randomized clinical trials and observational studies in the assessment of drug safety. *Rev Epidemiol Sante Publique*, 66(3):217\_225.

Kim WJ, Lee JS, Lee CK, Cheong HJ, Kim M, Sawchik Monegal J, Carneiro R, Kyaw MH, Haguinet F, Ray R, Matias G, 2017. Clinical features of influenza and acute respiratory illness in older adults at least 50 years of age in an outpatient setting in the Republic of Korea: a prospective, observational, cohort study. *J Korean Med Sci*. 32(3): 407\_14.

de Fays L, Van Malderen K, De Smet K, Sawchik J, Verlinden V, Hamdani J, Dogné JM, Dan B, 2015. Use of paracetamol during pregnancy and child neurological development. *Dev Med Child Neurol*, 57(8):718\_24.

Lin T\_Y, Hwang KP, Liu C\_C, Tang RB, Lin CY, Thapa K, Sawchik J, Pirçon J\_Y, Van Dyke M, Liu YF, Huang L\_M, Hausdorff W., 2013. Etiology of empyema thoracis and parapneumonic pleural effusion in Taiwanese children and adolescents younger than 18 years of age. *The Pediatric infectious disease journal* 32 (4): 419\_21. Tavares F, Nazareth I, Sawchik J, Kolte I, Verstraeten T, Bauchau V, 2011. Pregnancy and safety outcomes in women vaccinated with an AS03\_adjuvanted split virion H1N1 (2009) pandemic influenza vaccine during pregnancy: a prospective cohort study. *Vaccine* 29 (37): 6358\_6365.

Sawchik J, Dufrière M, Lebrun P, 2003. Estimation of habitat quality and evaluation of isolation effects in a butterfly population network, *Acta Oecologica* 24 (1): 25\_33. Sawchik J, Dufrière M, Lebrun P, Schtickzelle N, Baguette M, 2002. Metapopulation dynamics of the bog fritillary butterfly: modelling the effect of habitat fragmentation, *Acta Oecologica* 23 (5): 287\_296.

### Projects

Participation in survey design, conduct & analysis for studying effectiveness of risk minimization measures (e.g., DHPC for perdolan). Participation as biostatistician in UCB phase I clinical trials (e.g., QT/QTc, bioequivalence, dose-ranging studies) Participation in analysis and review of results of the study "Levocetirizine does not prolong the QT/QTc interval in healthy subjects: results from a thorough QT study" by Hulhoven R, Rosillon R, Letiexhe M, Meeus M\_A, Daoust A, Stockis A, Eur J Clin Pharmacol (2007) 63:1011–1017 Participation as biostatistician in GSK epidemiological studies (e.g., PASS, effectiveness, aetiological studies).

### Memberships

### Other Relevant Information

ICH\_GCP Whitehall Training (2018)

SMCS (UCL) Préparation et mise en place d'une enquête (SMCS)

EUNTC/AEMPS Advanced Pharmacoepidemiology with Case Studies (2017)

HMA/EMA Big Data Workshop (2017) BSWP Workshops: Statistical principles for clinical trials on choosing appropriate estimands and defining sensitivity analyses in clinical trials (2016), Subgroups in confirmatory clinical trials (2014)

Erasmus Summer Programme: Introduction to Bayesian Methods in Clinical Research (2017), Causal inference, Pharmacoepidemiology (2014), Cohort studies, Case\_control studies (2009)

Erasmus Winter Programme: Principles of epidemiologic data analysis (2016)

UCL Competing risks: a practical perspective (2008)

University of Edinburgh Mixed models analysis of medical data using SAS (2006)

UCB Medical writing workshop (2005)

SAS Certified Professional Program (2004)