

Curriculum Vitae

Personal information **Laura Sottosanti**

Work experience

Employer: Italian Medicines Agency (AIFA)

- Start date: 032023
- End date:
- Position: Head of Signal Management Office
- Activities: Coordination of AIFA activities aimed at monitoring and evaluating of Adverse Drug Reactions (ADR) and detection-management of safety signals. This includes the coordination of PhV Regional Centers. IT development systems supervisor for pharmacovigilance
- Country: Italy

Employer: Italian Medicines Agency (AIFA)

- Start date: 012005
- End date: 022023
- Position: Senior Safety Assessor
- Activities: Evaluation benefit-risk profile of medicinal products for human use through the assessment of several pharmacovigilance regulatory documents/procedures/activities. Safety Monitoring of clinical trials conducted in Italy and coordinator of the SUSAR project. Inspector for PhV inspections. Italian Trusted deputy for Eudravigilance. Responsible of Pharmacovigilance Quality System of the Office. Reference Person at national level for pharmacovigilance BEMA activity.
- Country: Italy

Employer: Ministry of Health

- Start date: 052000
- End date: 122004
- Position: Safety Assessor
- Activities: Evaluation of the benefit-risk profile of medicinal products for human use through the assessment of several regulatory documents/procedures/activities. Safety Monitoring of clinical trials conducted in Italy.
- Country: Italy

Employer: Civic Hospital of Palermo

- Start date: 011994
- End date: 021997
- Position: Hospital Pharmacist
- Activities: Hospital Pharmacist specialist on Artificial nutrition, antibiotic therapy and pharmacokinetics
- Country: Italy

Employer: Pharmacies

- Start date: 031994
- End date: 042000
- Position: Pharmacist
- Activities: Pharmacist in different pharmacies in
- Country: Italy

Education and training

Subject: University of Perugia _ Faculty of Engineering

- Start date: 012022
- End date: 072023
- Qualification: Master's Degree level II in Management of Healthcare Processes
- Organisation:
- Country: Italy

Subject: Catholic University of the Sacred Heart of Rome _ Faculty of Medicine

- Start date: 092009
- End date: 092010
- Qualification: Master's Degree level II in Pharmaceutical preclinical and clinical Development, technical, scientific, regulatory and ethical aspects
- Organisation:
- Country: Italy

Subject: University of Palermo _ Faculty of Pharmacy

- Start date: 011994
- End date: 121997
- Qualification: Major in Hospital Pharmacy (50/50 cum laude) with a training period in France
- Organisation:
- Country: Italy/France

Subject: University of Palermo _ Faculty of Pharmacy

- Start date: 091989
- End date: 071993
- Qualification: PharmD degree (110/110 cum laude)

- Organisation: Degree of Pharmacy Thesis: “The compounds of aromatic heterocycles five terms as intermediates in organic synthesis”.
- Country: Italy

Additional information

Publications

1. Is PEGylation of Drugs Associated with Hypersensitivity Reactions? An Analysis of the Italian National Spontaneous Adverse Drug Reaction Reporting System.
Crisafulli S, Cutroneo PM, Luxi N, Fontana A, Ferrajolo C, Marchione P, Sottosanti L, Zanoni G, Moretti U, Franzè S, Minghetti P, Trifirò G. *Drug Saf.* **2023 Apr**;46(4):343-355
2. Signal management and risk minimization strategy: a case study on obinutuzumab and non-overt disseminated intravascular coagulation
Valdiserra G, Sottosanti L. et al. *Drug Saf. Regul.*, 17 July **2023**, Volume 3
3. Safety Profile of Vitamin D in Italy: An Analysis of Spontaneous Reports of Adverse Reactions Related to Drugs and Food Supplements
Valentina Maggini, Giada Crescioli, Ilaria Ippoliti, Eugenia Gallo, Francesca Menniti-Ippolito, Adelaide Chiaravalloti, Vittorio Mascherini, Roberto Da Cas, Simona Potenza, Giulia Gritti, Maria Teresa Galiulo, Laura Sottosanti, Alfredo Vannacci, Niccolò Lombardi, Fabio Firenzuoli. *J. Clin. Med.* **2023**, 12, 4726
4. Drug-induced Urinary Retention: An Analysis of a National Spontaneous Adverse Drug Reaction Reporting Database.
Crisafulli S, Cutroneo PM, Verhamme K, Ferrajolo C, Ficarra V, Sottosanti L, Di Giovanni V, Spina E, Trifirò G. *Eur Urol Focus.* **2022 Sep**;8(5):1424-1432.
5. Relationship between injection site reactions and different adalimumab formulations. Analysis of the adverse events reported in Italy in the period 2016-2019.
Pilunni D, Santuccio C, Sottosanti L, Felicetti P, Navarra P. *Eur Rev Med Pharmacol Sci.* **2021 Apr**;25(8):3300-3305. doi: 10.26355/eurrev_202104_25468.PMID: 33928613
6. Drug Safety in Geriatric Patients: Current Status and Proposed Way Forward.
Furlan G, Caduff-Janosa P, Sottosanti L, Cappello E, Valdiserra G, Tuccori M. *Drug Saf.* **2020 Sep**;43(9):853-866. doi: 10.1007/s40264-020-00949-w.PMID: 32500271
7. Ototoxic Adverse Drug Reactions: A Disproportionality Analysis Using the Italian Spontaneous Reporting Database.
Barbieri MA, Cicala G, Cutroneo PM, Mocciaro E, Sottosanti L, Freni F, Galletti F, Arcoraci V, Spina E. *Front Pharmacol.* **2019 Oct 8**;10:1161. doi: 10.3389/fphar.2019.01161. eCollection 2019.PMID: 31649536
8. Manuale teorico-pratico sulla sperimentazione clinica farmacologica in Italia
Buccelli C., Cannavo Nunzia (Sottosanti L. autore del capitolo 9)

- Libro realizzato da Università degli Studi di Napoli Federico II e SIMLA c il patrocinio della Regione Campania. **2019**
9. Overview of the Safety of Anti-VEGF Drugs: Analysis of the Italian Spontaneous Reporting System.
Cutroneo PM, Giardina C, Ientile V, Potenza S, Sottosanti L, Ferrajolo C, Trombetta CJ, Trifirò G. *Drug Saf.* **2017** Nov;40(11):1131-1140. doi: 10.1007/s40264-017-0553-y.PMID: 28585152 Review.
 10. Safety of Antiplatelet Agents: Analysis of 'Real-World' Data from the Italian National Pharmacovigilance Network.
Gozzo L, Navarria A, Benfatto G, Longo L, Mansueto S, Sottosanti L, Pani L, Salomone S, Drago F. *Clin Drug Investig.* **2017** Nov;37(11):1067-1081. doi: 10.1007/s40261-017-0566-4.PMID: 28856572
 11. Italian monitoring registries: a tool for a safer use of innovative drugs? Data from the national pharmacovigilance system.
Magro L, Arzenton E, Moretti U, Sottosanti L, Potenza S, Leone R. *Expert Opin Drug Saf.* **2016** Dec;15(sup2):69-75. doi: 10.1080/14740338.2016.1248942.PMID: 27875920
 12. Ibuprofen-associated hypothermia in children: analysis of the Italian spontaneous reporting database.
Donati M, Monaco L, Melis M, Sottosanti L, Biagi C, Vaccheri A, Motola D. *Eur J Clin Pharmacol.* **2016** Oct;72(10):1239-1243. doi: 10.1007/s00228-016-2088-z. Epub 2016 Jul 14.PMID: 27417946
 13. How did the Introduction of Biosimilar Filgrastim Influence the Prescribing Pattern of Granulocyte Colony-Stimulating Factors? Results from a Multicentre, Population-Based Study, from Five Italian Centres in the Years 2009-2014.
Marcianò I, Ingrassiotta Y, Giorgianni F, Bolcato J, Chinellato A, Pirolo R, Di Giorgio A, Manna S, Ientile V, Gini R, Santarpia M, Genazzani AA, Uomo I, Pastorello M, Pollina Addario SW, Scondotto S, Cananzi P, Da Cas R, Traversa G, Rossi M, Sottosanti L, Caputi AP, Trifirò G. *BioDrugs.* **2016** Aug;30(4):295-306. doi: 10.1007/s40259-016-0175-4.PMID: 27138636
 14. Adverse drug reactions associated with off-label use of ketorolac, with particular focus on elderly patients. An analysis of the Italian pharmacovigilance database and a population based study.
Viola E, Trifirò G, Ingrassiotta Y, Sottosanti L, Tari M, Giorgianni F, Moretti U, Leone R. *Expert Opin Drug Saf.* **2016** Dec;15(sup2):61-67. doi: 10.1080/14740338.2016.1221401.PMID: 27875919
 15. Off-label use of nicardipine as tocolytic and acute pulmonary oedema: a post-marketing analysis of adverse drug reaction reports in EudraVigilance.
Melis M, Cupelli A, Sottosanti L, Buccellato E, Biagi C, Vaccheri A, Motola D. *Pharmacoepidemiol Drug Saf.* **2015** Nov;24(11):1220-4. doi: 10.1002/pds.3782. Epub 2015 Apr 2.PMID: 25845714

16. Safety profile of biological medicines as compared with non-biologicals: an analysis of the Italian spontaneous reporting system database.
Cutroneo PM, Isgrò V, Russo A, Ientile V, Sottosanti L, Pimpinella G, Conforti A, Moretti U, Caputi AP, Trifirò G. *Drug Saf.* **2014** Nov;37(11):961-70. doi: 10.1007/s40264-014-0224-1.PMID: 25255847
17. Bisphosphonate-related osteonecrosis of the jaw: an Italian post-marketing surveillance analysis.
Parretta E, Sottosanti L, Sportiello L, Rafaniello C, Potenza S, D'Amato S, González-González R, Rossi F, Colella G, Capuano A. *Expert Opin Drug Saf.* **2014** Sep;13 Suppl 1:S31-40. doi: 10.1517/14740338.2014.951329.PMID: 25171157
18. Safety profile of antiviral medications: a pharmacovigilance study using the Italian spontaneous-reporting database.
Pugi A, Bonaiuti R, Maggini V, Moschini M, Tuccori M, Leone R, Rossi M, Motola D, Piccinni C, Ferrazin F, Sottosanti L, Mugelli A, Vannacci A, Lapi F. *Am J Health Syst Pharm.* **2013** Jun 15;70(12):1039-46. doi: 10.2146/ajhp120665.PMID: 23719881
19. Adverse drug reaction reporting by nurses: analysis of Italian pharmacovigilance database.
Conforti A, Opri S, D'Incau P, Sottosanti L, Moretti U, Ferrazin F, Leone R. *Pharmacoepidemiol Drug Saf.* **2012** Jun;21(6):597-602. doi: 10.1002/pds.3225. Epub 2012 Feb 15.PMID: 22337264
20. Drug-induced taste and smell alterations: a case/non-case evaluation of an Italian database of spontaneous adverse drug reaction reporting.
Tuccori M, Lapi F, Testi A, Ruggiero E, Moretti U, Vannacci A, Bonaiuti R, Antonioli L, Fornai M, Giustarini G, Scollo C, Corona T, Ferrazin F, Sottosanti L, Blandizzi C. *Drug Saf.* **2011** Oct 1;34(10):849-59. doi: 10.2165/11593120-000000000-00000.PMID: 21879779
21. Adverse Drug Reactions. Suspect and Diagnosis
Caputi A.P., De Ponti F, Pagliaro L, Sottosanti L, et al.
Book with the patronage of the Italian Society of Pharmacology. Raffaello Cortina Editore. **2009**
22. Drug-related deaths: an analysis of the Italian spontaneous reporting database.
Leone R, Sottosanti L, Luisa Iorio M, Santuccio C, Conforti A, Sabatini V, Moretti U, Venegoni M. *Drug Saf.* **2008**;31(8):703-13. doi: 10.2165/00002018-200831080-00007.PMID: 18636789
23. Home therapy with elastomeric infusomeric. Experience of the Cystic Fibrosis Center of Palermo
Di Salvo L, Pardo F, Iapichino L, Mantione L, Lucania A, Sottosanti L, Micci A, Marrone P
Giornale Italiano di Farmacia Clinica (Italian Journal of Clinical Pharmacy): Pag 64, Vol 8, N.2 April-June **1994**

Author of numerous abstracts presented at conferences, articles on AIFA Drug Information Bulletin (BIF) and AIFA Pharmacovigilance Bulletin Reactions (Reazioni).

Projects

Memberships

- Italian Member of the Signal Management Review Technical working group (SMART WG - EMA);
- Italian Member of Pharmacovigilance Business Team (EMA);
- Italian representative in several meetings of the European Commission for the discussion on new pharmacovigilance legislation, of the Expert group on the delegated acts;
- Italian representative in several meetings of the Standing Committee on Human Medicinal Products of the European Commission Health And Consumers Directorate-General;
- Italian contact point for the WHO Programme for International Drug Monitoring
- Italian contact point for MedDRA (Medical Dictionary for Regulatory Activities) developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH));
- Italian Responsible Person (RP) for Eudravigilance
- Reference person at national level for pharmacovigilance for BEMA (Benchmarking of European Medicines Agencies) activity
- Active member of the Secretariat Coordination and Support of Research and Clinical Trials Office of AIFA and of the Secretariat Coordination and Support of PhV Office
- Representative for AIFA at the technical working group on the protection and promotion of health in the first 1000 days of life: from conception to two years of age" established by decree of the Director General of Health Prevention of the Ministry of Health of 26 July 2016

Other Relevant Information

- Lecturer on Pharmacovigilance topics in several (>10) Italian University post-graduates courses (Master di secondo livello)
- Invited Speaker in several national and international Conferences/Congress/Courses on Pharmacovigilance and Regulatory Affairs