

PERSONAL INFORMATION

Lucia Gozzo

[Redacted]
 99334223710 [Redacted]
 lucia.gozzo@unict.it | [Redacted]

Gender F | Date of birth [Redacted] Nationality Italian

WORK EXPERIENCE

- March 2018-Present: Expert consultant for Italian Medicines Agency (AIFA; Rome, Italy).
- JAN 2018-Present Cooperation with Monitoring Registries Office, AIFA (Rome, Italy).
- AUG 2018 – FEB 2019 Fellow at the Clinical Pharmacology Unit, University Hospital Policlinico Vittorio-Emanuele, Catania; Supervisor: Prof. Filippo Drago,
- MAY 2011 – DEC 2017 Cooperation with the Regional Pharmacovigilance Center (Catania, Italy), in particular for the appropriateness of drug use in pregnancy and lactation and in conducting studies on pharmacovigilance database; Supervisor: Prof. Filippo Drago
- JULY 2015-DEC 2017: Medical specialist at UNIFARM Research Center, Catania (Contract Research Organization); Supervisor: Prof. Salvatore Salomone Department of Biomedical and Biotechnological Sciences – Section of Pharmacology – University of Catania.
- SEPT 2012 –DEC 2017 Cooperation with the Clinical Pharmacology Unit, University Hospital Policlinico Vittorio-Emanuele, Catania; Supervisor: Prof. Filippo Drago,
- JUNE 2012-2015: Consultant for evaluation of dossiers for National and Regional drug approval developed at the University of Catania. Supervisor: Prof. Filippo Drago
- JULY 2014- DEC 2017: Cooperation with technical-scientific Office of Ethics Committee Catania 1, including clinical trials assessment in the Voluntary Harmonisation Procedure (VHP) project; Supervisor: Prof. Filippo Drago.
- MARCH 2016- DEC 2016 Collaboration at the project Interdrugs, (<http://www.interdrugs.it>) aimed at the study of clinically significant interactions between antiretroviral agents and other drugs.
- OCT 2015/JULY 2016 Clinical data management supervision and medical and regulatory support for FDA site inspection at the 'International Center for Transplantation in Thalassemia and Sickle Cell Anemia, Mediterranean Institute of Hematology (Transplant Unit IME), Policlinic of the University of Tor Vergata (Roma).

EDUCATION AND TRAINING

- March 2018: *Master in Regulatory Field*, XI edition; *magna cum laude* University of Catania. Title of Thesis: "Quality of life assessment in psychiatric drug approval: need to overcome an unmet regulatory need"
- JULY 2016 *Specialist in Clinical Pharmacology*, *magna cum laude*; University of Catania. Title of Thesis: "Linking the price of cancer drug treatments to their clinical value".
- JULY 2010 *Medical Doctor Degree*, *magna cum laude*; University of Catania. Title of diploma Thesis: "Behavioral effects of CDK inhibition in an animal model of memory loss induced by beta-amyloid."
- 2013-2014 Internship at the Department of Internal Medicine of Gaspare Rodolico University Hospital, Catania, Italy. Supervisor: Prof. Gaetano Bertino, professor of Internal Medicine – University of Catania
- 2012 Internship at the Department of Internal Medicine of Gaspare Rodolico University Hospital, Catania, Italy. Supervisor: Prof. Pietro Castellino, professor of Internal Medicine – University of Catania
- 2008 – 2009: Internship at the Department of Pediatric Hemato-Oncology and Bone Marrow Transplant Unit of Gaspare Rodolico University Hospital, Catania, Italy. Supervisor: Prof. Andrea Di Cataldo, professor of Pediatrics – University of Catania.

PERSONAL SKILLS

Mother tongue
Other language

Italian
English

UNDERSTANDING		SPEAKING		WRITING
Listening	Reading	Spoken interaction	Spoken production	
C1	C1	B2	B2	C1
Replace with name of language certificate. Enter level if known.				

Levels: A1/A2: Basic user - B1/B2: Independent user - C1/C2 Proficient user
[Common European Framework of Reference for Languages](#)

Job-related skills

Pharmacovigilance; evaluation of drug-drug interactions; drug use appropriateness in specific population (women of child-bearing potential or pregnant, children) and under specific conditions (under monitoring registries, off-label use, compassionate use); evaluation of risk/benefit and cost/effectiveness of high cost-drugs.

Experience in the preparation, evaluation and submission of the dossier for new drug application (National submission, price and reimbursement negotiations).

Experience in clinical trial design (phase 1-4 clinical trials including observational studies, studies with diet supplements and devices), conduct and reporting (including ADR reporting) developed at UNIFARM Research Center and during the cooperation with ethics committees. Clinical trials assessment in the VHP project (AIFA consultant).

Interaction with Italian Health Authorities and ethics committees related to preparation and submission of Clinical Trial Application packages and medical support to FDA inspection to clinical sites.

Experience in preclinical research in the field of neuroscience, including common laboratory techniques (Western Blot, immunoassays, PCR and sequencing) and behavioral tests

Computer skills

Excellent knowledge of National Pharmacovigilance Network (RNF) and Eudravigilance;
Excellent knowledge of Osservatorio Nazionale sulla Sperimentazione Clinica dei Medicinali;
Excellent knowledge of AIFA Monitoring Registries;
Excellent knowledge of Windows and Office software (Word, Excel, Power point).

Other skills

Basic life support procedures (Certification date: November 2019)

Driving licence

B

Publications and Congress

- L. Gozzo, P.P. Olimpieri, L. Longo, D.C. Vitale, F. Drago
Vitamin K antagonists (VKAs) and novel oral anticoagulants (NOACs) safety comparison based on data from EudraVigilance database
Ongoing publication
- Gozzo L., Di Lenarda A., Mammarella F., Olimpieri P.P., Cirilli A., Cuomo M., Gulizia MM, Colivicchi F., Murri G., Gabrielli D., Trotta F.
Starting dose and dose adjustment of Non-vitamin K antagonist oral anticoagulation agents in a nationwide cohort of patients with atrial fibrillation
Ongoing publication
- Olimpieri P.P., Di Lenarda A., Mammarella F., Gozzo L., Cirilli A., Cuomo M., Gulizia MM., Colivicchi F., Murri G., Gabrielli D., Trotta F.
Non-vitamin K antagonist oral anticoagulation agents in patients with atrial fibrillation: Insights from Italian Monitoring Registries
IJC Heart & Vasculature 2020
- C. Sipeky, A. Llerena, V. G. Manolopoulos, E. Pearson, V. Mlakar, L. Gozzo, M. Simmaco, P. Marchetti, R. Danesi, S. Stankovic, U. Meyer, I. Cascorbi, M. Ingelman-Sundberg, G. Suarez-Kurtz, J. Marc, T. Katsilla, M. Paulmichl, C. Nofziger, M. Ansari, F. Drago, R.H.N. van Schaik
4TH ESPT CONFERENCE: Pharmacogenomics and Personalised Medicine - research progress and clinical implementation.
Pharmacogenomics. 2019
- L. Gozzo, P.P. Olimpieri, F. Mammarella, M. Cuomo, A. Cirilli, A. Di Lenarda, D. Gabrielli, M. Gulizia, F. Colivicchi, G. Murri, F. Trotta
Oral Communications Atrial Fibrillation And Stroke
C4 Starting Dose Of Non-Vitamin K Antagonist Oral Anticoagulation Agents In Patients With Atrial Fibrillation: Data From Italian Monitoring Registries
European Heart Journal Supplements, Volume 21, Issue Supplement_E, May 2019, Pages E7–E10,
<https://doi.org/10.1093/eurheartj/suz097>
- F. Mammarella, P.P. Olimpieri, L. Gozzo, M. Cuomo, A. Cirilli, A. Di Lenarda, D. Gabrielli, M. Gulizia, F. Colivicchi, G. Murri, F. Trotta
E-Poster Stroke And Cardioembolism 1
NOACS: How Are They Used In Italy? Data From The AIFA Monitoring Registries
European Heart Journal Supplements, Volume 21, Issue Supplement_E, May 2019, Page E110,
<https://doi.org/10.1093/eurheartj/suz133>
- Bucolo C, Gozzo L., Longo L, Mansueto S, Vitale DC, Drago F.
Long-term efficacy and safety profile of multiple injections of intravitreal dexamethasone implant to manage diabetic macular edema: A systematic review of real-world studies.
J Pharmacol Sci. 2018 Dec;138(4):219-232. doi: 10.1016/j.jphs.2018.11.001. Epub 2018 Nov 20. Review.
- F.Megerlin, L. Gozzo, F. Drago, F. Lhoste
Païement « au r sultat » de m dicaments innovants : regards crois s franco-italiens
Techniques-hospitalieres. • Septembre-Octobre 2018
- Pratic  AD, Longo L, Mansueto S, Gozzo L., et al.
Off-Label use of drugs and adverse drug reactions in pediatric units: a prospective, multicenter study
Curr Drug Saf. 2018 Jun 19. doi: 10.2174/1574886313666180619120406. [Epub ahead of print]
- Gozzo L., Navarra A, Benfatto G, Longo L, Mansueto S, Sottosanti L, Pani L, Salomone S, Drago F
Clinical Drug Investigation. 2017 Aug 30. [Epub ahead of print]
Safety of antiplatelet agents: Analysis of "real-world" data from the Italian National Pharmacovigilance Network
- Gozzo L.¹, Navarra A¹, Drago V, Longo L, Mansueto S, Pignataro G, Cicchetti A, Salomone S, Drago F
Clinical Drug Investigation. July 2016, Volume 36, Issue 7, pp 579-589. ¹Equal contribution.
Linking the price of cancer drug treatments to their clinical value.
- Navarra A¹, Drago V¹, Gozzo L.¹, Longo L, Mansueto S, Pignataro G, Drago F. Value in Health. June 2016 Volume 19, Issue 4, Page 510. ¹Equal contribution.
Response to Letter to the Editor by Dr. Garattini.
- Leggio GM, Catania MV, Puzzo D, Spatuzza M, Pellitteri R, Gulisano W, Torrisi SA, Giurdanella G, Piazza C, Impellizzeri AR, Gozzo L., Navarra A, Bucolo C, Nicoletti F, Palmeri A, Salomone S, Copani A, Caraci F, Drago F. Pharmacol Res. 2016 Apr;106:10-20. Epub 2016 Feb 10.
The antineoplastic drug flavopiridol reverses memory impairment induced by Amyloid-β1-42 oligomers in mice.
- Navarra A¹, Drago V¹, Gozzo L.¹, Longo L, Mansueto S, Pignataro G, Drago F. Value in Health, Vol. 18, Issue 1, p131–136 ¹Equal contribution.

Do the Current Performance-Based Schemes in Italy Really Work? “Success Fee”: A Novel Measure for Cost-Containment of Drug Expenditure.

Navarria A, Tamburella A, Iannotti FA, Micale V, Camillieri G, Gozzo L, Verde R, Imperatore R, Leggio GM, Drago F, Di Marzo V.

The dual blocker of FAAH/TRPV1 N-arachidonoylserotonin reverses the behavioral despair induced by stress in rats and modulates the HPA-axis.

Pharmacol Res. 2014 May 23. PubMed PMID: 24861565

H-Index: 4

Section Monitoring Registries: V. Angelini, A. Cirilli, A. Colatrella, M. Cuomo, L. Gozzo, P.P. Olimpieri, D. Ricagni, G. Murri

The Medicines Utilisation Monitoring Centre. National Report on Medicines use in Italy. Year 2018. Rome: Italian Medicines Agency, 2019

Coworker SIF Regulatory news (Monthly newsletter edited by the Italian Society of Pharmacology) JULY 2014-Present

Coworker SIF Pharmacogenetics (Monthly newsletter edited by the Working Group on Pharmacogenetics of the Italian Society of Pharmacology) NOV 2011-Present

Farmacologia. Principi di base e applicazioni terapeutiche. F. Rossi, V. Cuomo, C. Riccardi.

Capitolo 18. Sviluppo ed uso dei farmaci: dal laboratorio alla clinica.

- Farmaci innovativi, farmaci “me too”, farmaci orfani, farmaci generici, farmaci non soggetti a prescrizione medica, dispositivi medici. F. Drago, L. Longo, L. Gozzo
- Metodologia di accesso ai farmaci a livello nazionale e internazionale. F. Drago, L. Longo, L. Gozzo.

Poster XXVIII Seminario Nazionale «La valutazione dell’uso e della sicurezza dei farmaci: esperienze in Italia».
Roma, 10/12/2019

L. Gozzo, P.P. Olimpieri, L. Longo, D.C. Vitale, F. Drago

Sicurezza degli anticoagulanti orali: analisi dei dati di Eudravigilance

Poster 39° National Congress of Italian Society of Pharmacology (SIF), 20 - 23 Nov 2019, Firenze, Italy

L. Gozzo, P.P. Olimpieri, L. Longo, D.C. Vitale, F. Drago

Safety of non-vitamin K antagonist oral anticoagulants and warfarin: analysis of EMA pharmacovigilance database reports.

Poster 39° National Congress of Italian Society of Pharmacology (SIF), 20 - 23 Nov 2019, Firenze, Italy

L. Longo, L. Gozzo, D.C. Vitale, G. Benfatto, F. Drago

Safety and cost of drugs prescribed according to Law 648/96

Poster 39° National Congress of Italian Society of Pharmacology (SIF), 20 - 23 Nov 2019, Firenze, Italy

D.C. Vitale, L. Gozzo, L. Longo, F. Drago

Use and expenditure of biological medicines at the University Hospital of Catania

Abstract ANMCO Congress 2019, Rimini, Italy

L. Gozzo, P. Olimpieri, F. Mammarella, M. Cuomo, A. Cirilli, A. Di Lenarda, D. Gabrielli, M. Gulizia, F. Colivicchi, G. Murri, F. Trotta

C4. Starting Dose Of Non-Vitamin K Antagonist Oral Anticoagulation Agents In Patients With Atrial Fibrillation: Data From Italian Monitoring Registries

Abstract ANMCO Congress 2019, Rimini, Italy

F. Mammarella, P. Olimpieri, L. Gozzo, M. Cuomo, A. Cirilli, A. Di Lenarda, D. Gabrielli, M. Gulizia, F. Colivicchi, G. Murri, F. Trotta

NOACS: How Are They Used In Italy? Data From The AIFA Monitoring Registries

Italian Society of Pharmacology (SIF) XXI Meeting 2018, Bresso, Italy

C.B.M. Platania, L. Gozzo, G. Benfatto, L. Longo, S. Mansueto, D.C. Vitale, A. Lazzara, F. Drago

Appropriateness and cost-effectiveness in drugs selection in the hospital setting: use of biosimilars at the University Hospital of Catania

Italian Society of Pharmacology (SIF) National Congress, Oct 25-28 2017, Rimini, Italy:

Posters

L. Gozzo, G. Benfatto, L. Longo, S. Mansueto, D.C. Vitale, A. Lazzara, F. Drago

Off-label drug use and safety of intravitreal anti-VEGF: data from Registries and Pharmacovigilance Network.

L. Gozzo, G. Benfatto, L. Longo, S. Mansueto, D.C. Vitale, A. Lazzara, F. Drago

Off-label drug use at the Policlinic-University Hospital of Catania, from 2012 to 2015: Focus on intra-ocular use of mitomycin

L. Gozzo, G. Benfatto, L. Longo, S. Mansueto, D.C. Vitale, A. Lazzara, F. Drago

Off-label drug use at the University Hospital of Catania: 2016 update.

L. Longo, G. Benfatto, L. Gozzo, S. Mansueto, D.C. Vitale, A. Lazzara, F. Drago

Ensure patients access to investigational medicines: compassionate use at the University Hospital of Catania

European Society of Pharmacogenomics and Personalised Therapy (ESPT) Congress 2017 (Oct 4-7 2017) Catania, Italy

L. Gozzo, G. Benfatto, L. Longo, S. Mansueto, D.C. Vitale, A. Lazzara, F. Drago

How many of them could be avoided? The importance of implementing pharmacogenetics into clinical practice

AOPT 2017 - 13TH SCIENTIFIC MEETING, Firenze, Italy:

Poster

L. Gozzo, L. Longo, S. Mansueto, F. Drago

Off-label drug use at the Policlinic-University Hospital of Catania, from 2012 to 2015: Focus on mitomycin C.

Italian Society of Pharmacology (SIF) XIX Meeting 2016, Rimini, Italy:

Poster

L. Gozzo, L. Longo, S. Mansueto, F. Drago

Off-label drug use: the experience of the University Hospital of Catania from 2012 to 2015

Italian Society of Pharmacology (SIF) National Congress 2015, Napoli, Italy:

Posters

L. Gozzo, A. Navarria, V. Drago, L. Longo, S. Mansueto, A. Cicchetti, F. Drago

Linking oncologic drug price to its value: the Italian proposal for a solution.

L. Gozzo, A. Navarria, V. Drago, L. Longo, S. Mansueto, G. Pimpinella, L. Pani, F. Drago

Comparative safety of antiplatelet agents: a study of "real-world" data from the Italian National Pharmacovigilance Network.

A. Navarria, V. Drago, L. Gozzo, L. Longo, S. Mansueto, G. Pignataro, F. Drago

Do the Current Performance-Based Schemes in Italy Really Work? "Success Fee": A Novel Measure for Cost-Containment of Drug Expenditure.

Italian Society of Pharmacology (SIF) National Congress 2013, Torino, Italy:

Poster

L. Longo, L. Gozzo, A.M. Navarria, T. Sinagra, V. Urso, F. Drago

Drug use during pregnancy: report from the Regional Pharmacovigilance Centre of Catania.

Conferences and awards

Speaker at the following congresses:

- Healthcare workers in the pharmacovigilance system: regulations and reporting (Presentation: "**Analysis by therapeutic area**"). Catania, 4 Aprile 2019
- Innovation in oncology: issues and sustainability (Presentation: "**Real-world data from Italian monitoring registries**"). Gravedona, 28 Settembre 2018
- Italian Society of Pharmacology (SIF) XXI Meeting 2018 (Presentation: "**Access to innovative drugs and not in Sicily: is it always guaranteed?**"). 19-22 September 2018, Bresso, Italy
- COFAS: Meeting La farmacologia siciliana, tra scienza e politica del farmaco (Presentation: "**Access to innovative drugs and not in Sicily: is it always guaranteed?**"). May 11-12 2018, Roccalumera, Italy
- COFAS Meeting: La farmacologia siciliana, tra scienza e politica del farmaco (Presentation: "**Tavola rotonda Pharmacovigilance in Sicily: Data from the Regional Pharmacovigilance Center of Catania**"). May 11-12 2018, Roccalumera, Italy
- New and old challenges for clinical pharmacology: from therapeutic drug monitoring to pharmacogenetics and pharmacovigilance (Presentation: "**How many of them could be avoided? The importance of implementing pharmacogenetics into clinical practice**"). March 15-16 2018, Napoli, Italy
- New therapies in immuno-oncology: how the cancer patients' journey will change, Catania, December 12 2017
- Chair of the ESPT RESEARCH GROUP PRESENTATIONS & DISCUSSION SESSIONS and member of the poster committee at the ESPT Congress 2017 (Oct 4-7 2017) Catania, Italy
- IL RUOLO DEL MEDICO NEL SISTEMA DI FARMACOVIGILANZA (Presentation: "**Casi clinici, compilazione della scheda di segnalazione di ADR e funzionamento della piattaforma Vigifarmaco**"). Catania, November 9 2017
- AOPT 2017 - 13TH SCIENTIFIC MEETING (Presentation: "**Off-label drug use in ocular pharmacology**"). Firenze, February 17 2017
- Monotematico SIF - Il ruolo della Farmacologia Clinica in Italia: prospettive future nell'ambito del SSN (Presentation: "**Off-label drug use in pediatric population: the experience of the**

University Hospital of Catania in 2012-2015 period). Napoli, December 15-16 2016

• **Drug Appropriateness** (Presentation: "**Drug Appropriateness in oncology**"). September 27 2014 Astoria Hotel Palace, Palermo, Italy

• **Pharmacovigilance days** (Presentation: "**Guide to adverse drug reaction report and National Pharmacovigilance Network**"). 11/06/2013, 02/07/2013, 23/07/2013, IDIPHARMA, Catania, Italy.

Winner SIF-Assogenerici Award 2016 with the project: "**Adverse drug reactions due to generic medicines: Impact of regional regulations about non-substitutability**"

Attendee at various Conferences and Meetings, including 3° and 4° Summer School of Clinical Pharmacology and award winner for the best protocol design– Stresa (Italy), 2015 and 2016.

I authorize the processing of my personal data pursuant to Italian Legislative Decree 30 June 2003, n. 196 "Code concerning the protection of personal data."

Aware of the fact that in case of mendacious declarations or falsity in the proceedings, will incur in the sanctions according to articles 75 and 76 of the Italian legislation n. 445/2000, I declare that the information provided is true.

Rome, 12/01/2020
Lucia Gozzo

