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Unit of Adverse Drug Reactions Monitoring  
University Hospital of Pisa  
Via Roma 55, 56126, Pisa, Italy

**Investigators****Prof. Marta Mosca**

Department of Clinical and Experimental Medicine  
Unit of Rheumatology  
University of Pisa  
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**Prof. Corrado Blandizzi**

Department of Clinical and Experimental Medicine  
Unit of Pharmacology and Pharmacovigilance  
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**Dr. Ersilia Lucenteforte**

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**Prof. Laura Baglietto**

Department of Clinical and Experimental Medicine  
Unit of Medical Statistics  
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Via Roma 55, 56126, Pisa, Italy

**Dr. Massimiliano Cazzato**

Unit of Rheumatology  
University Hospital of Pisa  
Via Roma 57, 56126, Pisa, Italy

**Dr Rosa Gini**

Agenzia regionale di sanita della Toscana  
Unit of Medical Informatics and Pharmacoepidemiology  
Via Pietro Dazzi 1, 50141, Firenze, Italy

**Dr Irma Convertino**

Department of Clinical and Experimental Medicine  
Unit of Pharmacology and Pharmacovigilance  
University of Pisa  
Via Roma 55, 56126, Pisa, Italy



## Declaration of Interests

### INTRODUCTION

This document includes your personal details and your declaration of interests to be made public in line with the provisions of the ENCePP Code of Conduct. All parts must be duly completed. You are responsible for the accuracy and completeness of the submitted information.

The form is designed to be filled in electronically; a copy of the form should be uploaded to the [EU PAS Register](#).

**For ENCePP Seal studies only:** the completed form is to be transmitted to the ENCePP Secretariat by email.

### SECTION 1: PERSONAL DETAILS

First Name:

Rosa

Last Name:

Gini

Organisation / Research Centre :

Agenzia regionale di sanita della Toscana  
Unit of Medical Informatics and Pharmacoepidemiology

Country:

Italy

Contact e-mail Address:

*rosa.gini@ars.toscana.it*

ExPloring efficacy, sAFeTy, and adHerence of disease-modiFyING antirheumatic Drugs through group-basEd tRajectory models: the PATHFINDER study

Study Reference Number: EUPAS

2 9 2 6 3

Are you the (Primary) Lead Investigator of the above study?

No  Yes

Are you an investigator/researcher contributing to the above study

No  Yes

## SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered.

### 2.1 Employment

No  Yes

#### Employment in a pharmaceutical company during past 3 years of study application?

Pharmaceutical company includes supply or service companies which contribute to research, development, production and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.

### 2.2 Financial Interest

No  Yes

#### Financial interests in the capital of a pharmaceutical company?

Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector.

### 2.3 Patent

No  Yes

#### Patent for a medicinal product?

Relates to a patent for a medicinal product currently owned by either you as individual or your organisation/ research centre, and you as individual are the beneficiary.

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Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

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Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.

## SECTION 3: ANY OTHER INTERESTS

No  Yes

### In this section you should declare any other interests of commercial, financial, institutional or personal nature to be made known to the public.\*

Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family? (\*see definition in Annex 1 of ENCePP Code of Conduct)

Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study.

Should there be any change of the above due to the fact that I acquire additional interests, I shall promptly complete and upload a new Declaration of Interests detailing the changes.

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the [EU PAS Register](#).

FULL NAME:

Rosa Gini

Date:

08/04/2019

Submit Form by Email

# Rosa Gini

Head of the Pharmacoepidemiology Unit

Agenzia regionale di sanità della Toscana, Via Dazzi 1, 50141, Florence, Italy

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+39 335 77 57 388

h-index: 17 (Scopus)

number of citations: 908 (Scopus)

## Summary

I am a data scientist focused on secondary use of electronic health records for pharmacoepidemiology and health services research. My specific interest is accurate, reliable, transparent and fast generation of evidence to support health policy making. I have experience in data integration from diverse data sources and data validation.

I am the Head of the Pharmacoepidemiology Unit of the Agenzia regionale di sanità della Toscana, a public health agency in Florence, Italy. My unit, comprising several units of personnel and contributors from the three Tuscan universities and from other Tuscan research centers, is involved in many observational studies on utilization, safety and effectiveness of drugs in Tuscany, in national or in multi-national networks of databases.

## Main Projects

In Tuscany I am responsible for conducting drug utilization, safety and comparative effectiveness studies of interest for decision making on drug policy. Currently, I am leading studies on drugs to treat non-small cell lung cancer, rituximab for ematologic cancers, incretins for type 2 diabetes, antivasular endothelial growth factor agents for retinal diseases, antirheumatic biologic drugs, cholesterol-lowering drugs, and others.

I am involved in the ADVANCE Project (Accelerated development of vaccine benefit-risk collaboration in Europe), an initiative funded by IMI (Innovative Medicine Initiative) developing a framework capable of rapidly delivering reliable data on the benefits and risks of vaccines that are on the market.

I was responsible for the activity of data quality and benchmarking of the EMIF Project (European Medical Information Framework), an initiative funded by IMI aimed at establishing a European infrastructure for observational studies from existing databases.

I belong to the core team of developers of TheMatrix, an open source software that supports data collection for multicentric studies in a distributed architecture (<http://thematrix.isti.cnr.it>). Using this infrastructure I am leading IMECCHI-DATANETWORK (<https://imecchi.net/imecchi-datanetwork/>), a distributed network spanning across 4 continents (Asia, Europe, Oceania and North America).

I was leader of several activities of the MATRICE project, an initiative of Agenas, the Italian National Agency for Regional Health Systems, aimed at testing secondary use of Italian health administrative databases for assessing healthcare quality for chronic diseases. The MATRICE project funded my PhD in Medical Informatics at the Erasmus University of Rotterdam.

I was responsible for data processing and analysis of Tuscan data for the European FP7-funded EUROmedCAT project, aimed at performing studies on drug utilization and drug safety in pregnancy in a network of European data sources.

I was involved in the EU-ADR project (Exploring and Understanding Adverse Drug Reactions by Integrative Mining of Clinical Records and Biomedical Knowledge, 2008-2012), a FP7-funded initiative aimed at exploiting different electronic health records databases for drug safety. I was particularly focused on semantic interoperability among different data sources.

I have been involved in several EMA tenders.

## Education

- Feb 2011 – Oct 2016* **PhD in Medical Informatics**  
Erasmus MC, Department of Medical Informatics  
Rotterdam, Netherlands
- Jan 1996 - April 2001* **PhD in Mathematics**  
Università di Pisa, Department of Mathematics  
Pisa, Italy
- Nov 1989-Jul 1995* **Master degree in Mathematics**  
Università degli studi di Milano, Dipartimento di Matematica  
Milan, Italy

## Skills & Activities

- Skills* Data processing (Stata, SQL, R, TheMatrix)  
Software design and evaluation
- Languages* Italian, English, French, Spanish, Portuguese
- Scientific Memberships* European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (elected member of the Steering Group, 2016 - current)  
International Society of Pharmacoepidemiology (co-lead of a Taskforce in the Database Special Interest Group)  
Italian Epidemiology Association (elected member of the Steering Group, 2010-2012)
- Interests* Pharmacoepidemiology, Data Science, Validation studies, Health Policy Evaluation, Muti-database studies

## PhD thesis

**Gini R.** *A Validation Odyssey: from big data to local intelligence.* Erasmus University Rotterdam; 2016.  
Available from: <http://hdl.handle.net/1765/93461>

## SELECTED PUBLICATIONS IN PEER-REVIEWED JOURNALS

### Data science, medical informatics and validation studies

- Trifirò G, **Gini R**, Barone-Adesi F, Beghi E, Cantarutti A, Capuano A, et al. *The Role of European Healthcare Databases for Post-Marketing Drug Effectiveness, Safety and Value Evaluation: Where Does Italy Stand?* Drug Saf. 2018 Sep 29. **IF: 3.643**
- Charlton RA, Bettoli V, Bos HJ, Engeland A, Garne E, **Gini R**, et al. *The limitations of some European healthcare databases for monitoring the effectiveness of pregnancy prevention programmes as risk minimisation measures.* Eur J Clin Pharmacol. 2017 Dec 11. **IF: 2.902**
- Gini R**, Schuemie MJ, Pasqua A, Carlini E, Profili F, Cricelli I, et al. *Monitoring compliance with standards of care for chronic diseases using healthcare administrative databases in Italy: Strengths and limitations.* PLoS ONE. 2017;12(12):e0188377.
- Perera G, Pedersen L, Ansel D, Alexander M, Arrighi HM, Avillach P, et al. *Dementia prevalence and incidence in a federation of European Electronic Health Record databases: The European Medical Informatics Framework resource.* Alzheimers Dement. 2017. **IF: 12.740**
- Wang SV, Schneeweiss S, Berger ML, Brown J, de Vries F, Douglas I, et al. *Reporting to Improve Reproducibility and Facilitate Validity Assessment for Healthcare Database Studies V1.0.* Pharmacoepidemiol Drug Saf. 2017 Sep;26(9):1018–32. **IF: 2.552**
- Gini R**, Schuemie MJ, Mazzaglia G, Lapi F, Francesconi P, Pasqua A, et al. *Automatic identification of type 2 diabetes, hypertension, ischaemic heart disease, heart failure and their levels of severity from Italian General Practitioners' electronic medical records: a validation study.* BMJ Open. 2016 Dec. **IF: 2.369**  
1;6(12):e012413.
- Roberto G, Leal I, Sattar N, Loomis AK, Avillach P, Egger P, van Wijngaarden R, Ansell D, Reisberg S, Tammesoo ML, Alavere H, Pasqua A, Pedersen L, Cunningham J, Tramontan L, Mayer MA, Herings R, Coloma P, Lapi F, Sturkenboom M, van der Lei J, Schuemie MJ, Rijnbeek P, **Gini R**. *Identifying cases of type 2 diabetes in heterogeneous data sources: strategy from the EMIF project.* PLoS ONE 2016;11(8):e0160648. **IF: 3.54**
- Gini R**, Schuemie M, Brown J, Ryan P, Vacchi E, Coppola M, et al. *Data Extraction And Management In Networks Of Observational Health Care Databases For Scientific Research: A Comparison Among EU-ADR, OMOP, Mini-Sentinel And MATRICE Strategies.* eGEMs (Generating Evidence & Methods to improve patient outcomes) 2016 ;4(1)
- Jonge L de, Garne E, **Gini R**, Jordan SE, Klungsoyr K, Loane M, et al. *Improving Information on Maternal Medication Use by Linking Prescription Data to Congenital Anomaly Registers: A EUROmediCAT Study.* Drug Saf. 2015;1–11. **IF: 3.206**
- De Bie S, Coloma PM, Ferrajolo C, Verhamme KMC, Trifirò G, Schuemie MJ, Straus SMJM, **Gini R**, et al. *The role of electronic healthcare record databases in paediatric drug safety surveillance: a retrospective cohort study.* Br J Clin Pharmacol. 2015 ;80(2):304-14. **IF: 3.83**

- Patadia VK, Coloma P, Schuemie MJ, Herings R, **Gini R**, Mazzaglia G, et al. *Using real-world healthcare data for pharmacovigilance signal detection - the experience of the EU-ADR project*. *Expert Rev Clin Pharmacol*. 2015;8(1):95–102. **IF: 2.488**
- Valkhoff VE, Coloma PM, Masclee GMC, **Gini R**, Innocenti F, Lapi F, et al. *Validation study in four health-care databases: upper gastrointestinal bleeding misclassification affects precision but not magnitude of drug-related upper gastrointestinal bleeding risk*. *Journal of clinical epidemiology* 2014;67(8):921–31. **IF: 3.417**
- Charlton RA, Neville AJ, Jordan S, Pierini A, Damase-Michel C, Klungsøyr K, Nybo Andersen AM, Hansen AV, **Gini R**, et al. *Healthcare databases in Europe for studying medicine use and safety during pregnancy*. *Pharmacoepidemiology and Drug Safety* 2014;23(6):586-94. **IF: 2.908**
- Gini R**, Schuemie MJ, Francesconi P, Lapi F, Cricelli I, Pasqua A, et al. *Can Italian healthcare administrative databases be used to compare regions with respect to compliance with standards of care for chronic diseases?* *PLoS ONE* 01/2014; 9(5):e95419. **IF: 3.54**
- Gini R**, Francesconi P, Mazzaglia G, Cricelli I, Pasqua A, Gallina P, et al. *Chronic disease prevalence from Italian administrative databases in the VALORE project: a validation through comparison of population estimates with general practice databases and national survey*. *BMC Public Health* 2013; 13(1):15. **IF: 2.209**
- Avillach P, Coloma PM, **Gini R**, Schuemie M, Mouglin F, Dufour J-C, et al. *Harmonization process for the identification of medical events in eight European healthcare databases: the experience from the EU-ADR project*. *Journal of the American Medical Informatics Association* 2013;20(1):184-92. **IF: 3.428**
- Schuemie MJ, **Gini R**, Coloma PM, Straatman H, Herings RMC, Pedersen L, et al. *Replication of the OMOP Experiment in Europe: Evaluating Methods for Risk Identification in Electronic Health Record Databases*. *Drug Safety*. 2013;36(S1):159–69. **IF: 3.206**
- Schuemie MJ, Coloma PM, Straatman H, Herings RMC, Trifirò G, Matthews JN, Prieto-Merino D, Molokhia M, Pedersen L, **Gini R**, Innocenti F, Mazzaglia G, Picelli G, Scotti L, van der Lei J, Sturkenboom M. *Using Electronic Health Care Records for Drug Safety Signal Detection: A Comparative Evaluation of Statistical Methods*. *Medical care* 2012; 50(10):890-897. **IF: 3.081**
- Coloma PM, Trifirò G, Schuemie MJ, **Gini R**, Herings R, Hippisley-Cox J, et al. *Electronic healthcare databases for active drug safety surveillance: is there enough leverage?*. *Pharmacoepidemiology and Drug Safety* 02/2012; 21(6):611-21. **IF: 2.908**
- Coloma PM, Schuemie MJ, Trifirò G, **Gini R**, Herings R, Hippisley-Cox J, et al. *Combining electronic healthcare databases in Europe to allow for large-scale drug safety monitoring: the EU-ADR Project*. *Pharmacoepidemiology and Drug Safety* 2011; 20(1):1-11. **IF: 2.908**

## **Pharmacoepidemiology**

- Roberto G, Barone-Adesi F, Giorgianni F, Pizzimenti V, Ferrajolo C, Tari M, et al. *Patterns and trends of utilization of incretin-based medicines between 2008 and 2014 in three Italian geographic areas*. *BMC Endocrine Disorders*. 2019 Feb 7;19(1):18. **IF: 2.411**
- Rea F, Calusi G, Franchi M, Vetrano DL, Roberto G, Bonassi S, et al. *Adherence of Elderly Patients with Cardiovascular Disease to Statins and the Risk of Exacerbation of Chronic Obstructive Pulmonary Disease: Evidence from an Italian Real-World Investigation*. *Drugs Aging*. 2018;35(12):1099–108.



- Marciandò I, Ingrasciotta Y, Giorgianni F, Ientile V, Chinellato A, Tari DU, et al. *Pattern of Use of Biosimilar and Originator Somatropin in Italy: A Population-Based Multiple Databases Study During the Years 2009–2014*. *Frontiers in Endocrinology*. March 2018. Available at: <http://journal.frontiersin.org/article/10.3389/fendo.2018.00095/full>
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- Roberto G, Bartolini C, Rea F, Onder G, Vitale C, Trifirò G, et al. *NSAIDs utilization for musculoskeletal indications in elderly patients with cerebro/cardiovascular disease*. *Eur J Clin Pharmacol*. 2018 Jan 30. **IF: 2.902**
- Vetrano DL, La Carpia D, Grande G, Casucci P, Bacelli T, Bernabei R, et al. *Anticholinergic Medication Burden and 5-Year Risk of Hospitalization and Death in Nursing Home Elderly Residents With Coronary Artery Disease..* 2016 Nov 1;17(11):1056–9. **IF: 5.775**
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- Charlton RA, Klungsøyr K, Neville AJ, Jordan S, Pierini A, Berg LTW de J den, Bos HJ, Puccini A, Engeland A, **Gini R**, et al. *Prescribing of Antidiabetic Medicines before, during and after Pregnancy: A Study in Seven European Regions*. *PLoS ONE*. 2016;11(5):e0155737. **IF: 3.54**
- Marciandò I, Ingrasciotta Y, Giorgianni F, Bolcato J, Chinellato A, Pirolo R, Di Giorgio A, Manna S, Ientile V, **Gini R**, et al. *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*. *BioDrugs*. 2016;30(4):295-306. **IF: 2.867**
- Charlton RA, Pierini A, Klungsøyr K, Neville AJ, Jordan S, Berg LTW de J den, Thayer D, Bos HJ, Puccini A, Hansen AV, **Gini R**, et al. *Asthma medication prescribing before, during and after pregnancy: a study in seven European regions*. *BMJ Open*. 2016;6(1):e009237. **IF: 2.562**
- Coloma PM, de Ridder M, Bezemer I, Herings RMC, **Gini R**, Pecchioli S, et al. *Risk of cardiac valvulopathy with use of bisphosphonates: a population-based, multi-country case-control study*. *Osteoporos Int*. 2015 27(5):1857-67. **IF: 3.445**
- Bezemer ID, Verhamme KMC, **Gini R**, Mosseveld M, Rijnbeek PR, Trifirò G, et al. *Use of oral contraceptives in three European countries: a population-based multi-database study*. *The European Journal of Contraception & Reproductive Health Care*. 2015;21(1):81-7 **IF: 1.236**
- Pacurariu AC, Straus SM, Trifirò G, Schuemie MJ, **Gini R**, Herings R, et al. *Useful Interplay Between Spontaneous ADR Reports and Electronic Healthcare Records in Signal Detection*. *Drug Saf*. 2015;38(12):1201-10. **IF: 3.206**

- Charlton R, Garne E, Wang H, Klungsøyr K, Jordan S, Neville A, Pierini A, Hansen A, Engeland A, **Gini R**, et al. *Antiepileptic drug prescribing before, during and after pregnancy: a study in seven European regions*. *Pharmacoepidemiol Drug Saf*. 2015. **IF: 2.908**
- Ingrasciotta Y, Giorgianni F, Bolcato J, Chinellato A, Pirolo R, Tari DU, Troncone C, Fontana A, Ientile V, **Gini R**, et al. *How Much Are Biosimilars Used in Clinical Practice? A Retrospective Italian Population-Based Study of Erythropoiesis-Stimulating Agents in the Years 2009-2013*. *BioDrugs*. 2015. **IF: 2.867**
- Charlton R, Jordan S, Pierini A, Garne E, Neville A, Hansen A, **Gini R**, et al. *Selective serotonin reuptake inhibitor prescribing before, during and after pregnancy: a population-based study in six European regions*. *BJOG* 2014 ;24(11):1144-54. **IF: 4.096**
- Masclee GM, Valkhoff VE, Coloma PM, de Ridder M, Romio S, Schuemie MJ, Herings R, **Gini R**, Mazzaglia G, Picelli G, Scotti L, Pedersen L, Kuipers EJ, van der Lei J, Sturkenboom M. *Risk for Upper Gastrointestinal Bleeding from Different Drug Combinations*. *Gastroenterology* 2014;147(4):784-792. **IF: 18.187**
- Ferrajolo C, Coloma PM, Verhamme KMC, Schuemie MJ, de Bie S, **Gini R**, et al. *Signal detection of potentially drug-induced acute liver injury in children using a multi-country healthcare database network*. *Drug Safety* 2014; 37(2):99-108. **IF: 3.206**
- Coloma PM, Schuemie MJ, Trifirò G, Furlong L, van Mulligen E, Bauer-Mehren A, Avillach P, Kors J, Sanz F, Mestres J, Oliveira JL, Boyer S, Helgee EA, Molokhia M, Matthews J, Prieto-Merino D, **Gini R**, Herings R, Mazzaglia G, Picelli G, Scotti L, Pedersen L, van der Lei J, Sturkenboom M. *Drug-Induced Acute Myocardial Infarction: Identifying 'Prime Suspects' from Electronic Healthcare Records-Based Surveillance System*. *PLoS ONE* 2013; 8(9). **IF: 3.54**

### **Health services research and policy evaluation**

- Buja A, Fusinato R, Claus M, **Gini R**, Braga M, Cosentino M, et al. *Diabetes management in the primary care setting: a comparison of physicians' performance by gender*. *Prim Health Care Res Dev*. June 2018;1-6.
- Barletta V, Profili F, **Gini R**, Grilli L, Rampichini C, Matarrese D, et al. *Impact of Chronic Care Model on diabetes care in Tuscany: a controlled before-after study*. *Eur J Public Health*. 2016. **IF: 2.571**
- Buja A, Solinas G, Visca M, Federico B, **Gini R**, Baldo V, et al. *Prevalence of Heart Failure and Adherence to Process Indicators: Which Socio-Demographic Determinants are Involved?* *International Journal of Environmental Research and Public Health*. 2016;13(2):238. **IF: 2.035**
- Buja A, **Gini R**, Visca M, Damiani G, Federico B, Donato D, et al. *Need and disparities in primary care management of patients with diabetes*. *BMC Endocrine Disorders*. 2014;14(1):56. **IF: 1.739**
- Buja A, Damiani G, **Gini R**, Visca M, Federico B, Donato D. *Systematic age-related differences in chronic disease management in a population-based cohort study: a new paradigm of primary care is required*. *PLoS ONE* 2014; 9(3):e91340. **IF: 3.54**
- Visca M, Donatini A, **Gini R**, Federico B, Damiani G, Francesconi P, et al. *Group versus single handed primary care: A performance evaluation of the care delivered to chronic patients by Italian GPs*. *Health Policy* 2013 113(1-2):188-98. **IF: 2.035**
- Buja A, **Gini R**, Visca M, Damiani G, Federico B, Francesconi P, et al. *Prevalence of chronic diseases by immigrant status and disparities in chronic disease management in immigrants: a population-based cohort study, Valore Project*. *BMC Public Health* 2013; 13(1):504. **IF: 2.209**

Carinci F, Roti L, Francesconi P, **Gini R**, Tediosi F, Di Iorio T, Bartolacci S, Buiatti E. *The impact of different rehabilitation strategies after major events in the elderly: the case of stroke and hip fracture in the Tuscany region*. BMC Health Services Research 2007; 7:95. **IF: 1.606**

### **Mathematics**

**Gini R**, Ornea L, Parton M, Piccinni P. *Reduction of Vaisman structures in complex and quaternionic geometry*. Journal of Geometry and Physics 2006;56 (12):2501-2522

**Gini R**, Ornea L, Parton M. *Locally conformal Kähler reduction*. Crelle's Journal 2005;(581):1-21.

Funar L, **Gini R**. *The Graded Cobordism Group of Codimension-One Immersions*. Geometric and Functional Analysis 2002; 12(6):1235-1264.

**Gini R**. *Cobordism of immersions of surfaces in non-orientable 3-manifolds*. manuscripta mathematica 2000; 104(1):49-69.



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### SECTION 1: PERSONAL DETAILS

First Name:

Last Name:

Organisation / Research Centre :

Country:

Contact e-mail Address:

Study Reference Number: EUPAS

Are you the (Primary) Lead Investigator of the above study? No  Yes

Are you an investigator/researcher contributing to the above study? No  Yes

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No  Yes

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Any other relationships/conditions/circumstances that present a potential conflict of interest, including matters relating to members of your family? (\*see definition in Annex 1 of ENCePP Code of Conduct)

Further to the interests declared above, I do hereby declare on my honour that I do not have any further interests or facts that should be made public in relation to the conduct of the study.

Should there be any change of the above due to the fact that I acquire additional interests, I shall promptly complete and upload a new Declaration of Interests detailing the changes.

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the [EU PAS Register](#).

FULL NAME:

Prof. Corrado Blandizzi

Date:

08/04/2019

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## **Corrado Blandizzi – Curriculum vitae**

**BIRTH PLACE AND DATE:** Melbourne (Australia), October 5th, 1961.

**CITIZENSHIP:** Italian.

**UNIVERSITY DEGREE:** Medicine and Surgery, with honours, School of Medicine and Surgery, University of Pisa (1988).

**CURRENT POSITIONS AT THE UNIVERSITY OF PISA:** 1) Chairman, Department of Clinical and Experimental Medicine (since 2016); 2) Full professor of Pharmacology, School of Medicine and Surgery (since 2010); 3) Member, Governing Board, University of Pisa (since 2016).

**CURRENT POSITIONS AT THE UNIVERSITY HOSPITAL OF PISA:** 1) Chairman, Center of Clinical Pharmacology for Drug Experimentation (since 2014); 2) Chief, Unit of Adverse Drug Reaction Monitoring (since 2011).

**OTHER POSITIONS:** 1) Member, Executive Committee, Italian Society of Pharmacology (since 2017); 2) Member, Executive Committee, GISMAD (The Italian Study Group of Digestive System Motility; from 2011 to 2015).

**PREVIOUS ACADEMIC POSITIONS:** 1) Assistant professor of Pharmacology, School of Medicine and Surgery, University of Pisa (from 1996 to 2000); 2) Associate professor of Pharmacology, School of Medicine and Surgery, University of Pisa (from 2000 to 2010); 3) Chairman, Interdepartmental Center for Research in Clinical Pharmacology and Experimental Therapeutics, University of Pisa (from 2009 to 2012); 4) President of Faculty, Graduation Program in Dentistry, University of Pisa (from 2011 to 2014); 5) Member, Internal Committee for Quality Assessment (from 2013 to 2016); 6) President of Faculty, Graduation in Medicine and Surgery (from 2014 to 2016); 7) Chairman, Postgraduate Course in Clinical Pharmacology and Toxicology (from 2014 to 2018).

**POSTGRADUATE EDUCATION:** 1) Degree with honours, Postgraduate School of Gastroenterology and Digestive Endoscopy, University of Pisa (1992); 2) Degree with honours, Postgraduate School of Clinical Pharmacology (1997).

**POSTGRADUATE INTERNSHIPS:** 1) Postdoctoral fellow, Division of Pharmacology and Chemotherapy, School of Medicine and Surgery, University of Pisa (research programme: Gastrointestinal pharmacology, 1998-1996); 2) Visiting fellow, Institute of Experimental Medicine, Hungarian Academy of Sciences, Budapest, Hungary (research programme: Pharmacological characterization of alpha-2 adrenoceptor subtypes in the gastrointestinal tract, 1991); 3) Postdoctoral fellow, Gastrointestinal Peptide Research Center, Department of Internal Medicine, University of Michigan Medical Center, Ann Arbor, Michigan, U.S.A. (advanced postdoctoral research fellowship programme issued by C.N.R.-N.A.T.O.; research programme: cloning and molecular biology of CCK-B/gastrin receptor gene, 1993-94).

**FIELDS OF SCIENTIFIC RESEARCH:** 1) Pharmacology of the gastrointestinal system; 2) Pharmacovigilance and pharmacoepidemiology of adverse drug reactions.

**MAIN RESEARCH TOPICS:** 1) Pharmacology of the gastrointestinal system: a) Pharmacological modulation of secretory and neuromotor functions of gastrointestinal tract; b) Pharmacological modulation of enteric neurotransmission in the presence of inflammatory processes; c) Pharmacological modulation and pathophysiology of gastrointestinal mucosal injury and protection; 2) Pharmacovigilance and pharmacoepidemiology of adverse drug

reactions: a) studies on databases of spontaneous adverse drug reaction reporting; b) studies of intensive monitoring of adverse drug reactions.

MAIN SOURCES OF RESEARCH GRANTS: 1) Italian Ministry of Education, University and Research; 2) University of Pisa; 3) Italian Medicines Agency-Tuscany Region; 4) Pharmaceutical Companies (investigator initiated research programs).

SCIENTIFIC PUBLICATIONS: 274 publications, including 230 full papers published on journals with impact factor subjected to peer review, 8 full papers published on journals without impact factor but subjected to peer review; 10 full papers published in Italian journals; 26 book chapters. H-index: 44.

ORGANIZATION OF SCIENTIFIC MEETINGS: 1) Functional disorders of the lower digestive tract: from the molecular bases to therapy, Pisa, November 11-12, 2011; 2) Osteoarthritis: from clinical pictures to targeted therapeutic strategies, Pisa, June 15-16, 2012; 3) Management of spontaneous reporting of adverse drug reactions in Italian health districts, Pisa, September 22, 2012; 4) 13<sup>th</sup> Annual Meeting of the International Society of Pharmacovigilance (ISoP), Pisa, October 1-4, 2013; 5) The pharmacological therapy of immune-mediated inflammatory diseases, first national congress, Bologna, March 5-7, 2015; 6) The pharmacological therapy of immune-mediated inflammatory diseases, second national congress, Bologna, April 12-14, 2018.

PATENTS: 1) Use of macrolides for treating intestinal inflammation, European Patent Office, Patent no. 06725052.2-2123-EP2006060709, March 14, 2006; designation: inventor/co-inventor; 2) NSAID administration and related composition, methods and systems, World Intellectual Property Organization – Patent Cooperation Treaty (WIPO-PCT), Patent no. WO2014/167533A1, October 16, 2014; designation: inventor.

AFFILIATIONS TO SCIENTIFIC SOCIETIES: 1) Italian Society of Pharmacology; 2) Italian Society of Neurogastroenterology and Motility; 3) American Society for Pharmacology and Experimental Therapeutics; 4) American Gastroenterological Association; 5) International Society of Pharmacovigilance; 6) Italian Purine Club.





## Declaration of Interests

### INTRODUCTION

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**For ENCePP Seal studies only:** the completed form is to be transmitted to the ENCePP Secretariat by email.

### SECTION 1: PERSONAL DETAILS

First Name:

Last Name:

Organisation / Research Centre :

Country:

Contact e-mail Address:

Study Reference Number: EUPAS

Are you the (Primary) Lead Investigator of the above study? No  Yes

Are you an investigator/researcher contributing to the above study? No  Yes

## SECTION 2: DECLARATION OF INTERESTS RELATED TO PHARMACEUTICAL INDUSTRY

In this section you must declare any interests in the pharmaceutical industry that you currently have or had within the past 3 years. If you have interests to declare please tick 'Yes' to the relevant questions. All questions in this part must be answered.

### 2.1 Employment

No  Yes

#### Employment in a pharmaceutical company during past 3 years of study application?

Pharmaceutical company includes supply or service companies which contribute to research, development, production and maintenance of a medicinal product. Employment relates to salaries currently being directly paid to you by a pharmaceutical company.

### 2.2 Financial Interest

No  Yes

#### Financial interests in the capital of a pharmaceutical company?

Financial interests relate to current holding of shares of a pharmaceutical company with the exclusion of independently managed investment funds/pensions schemes that are not exclusively based on the pharmaceutical sector.

### 2.3 Patent

No  Yes

#### Patent for a medicinal product?

Relates to a patent for a medicinal product currently owned by either you as individual or your organisation/ research centre, and you as individual are the beneficiary.

### 2.4 Consultancy

No  Yes

#### Consultancy for a pharmaceutical company during the past 3 years of study application?

Consultancy refers to provision of advice or services to a pharmaceutical company excluding the concerned study and including but not limited to reviewing activities, data monitoring, statistical analysis, end point committees, regardless of contractual arrangements or any form of remuneration such as consulting fees or honoraria.

Note that conference/seminar attendance is not considered a consultancy but should be indicated if subject to fee or honorarium.

### 2.5 Strategic Advisory Role

No  Yes

#### Strategic Advisory role on activities of a pharmaceutical company during the past 3 years of study application?

Participation with the right to vote on/influence the output in a (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the future strategy, direction or development activities of a pharmaceutical company either in terms of general or product-related strategy, regardless of contractual arrangements or any form of remuneration.

### 2.6 Grant / Funding

No  Yes

#### Grant/funding from a pharmaceutical company other than funds contemplated in the concerned study contract?

Refers to a grant or funding from a pharmaceutical company which is currently being received by your research group, irrespective of whether you are employed or a volunteer, and you receive no personal gain.

## SECTION 3: ANY OTHER INTERESTS

No  Yes

### In this section you should declare any other interests of commercial, financial, institutional or personal nature to be made known to the public.\*

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FULL NAME:

Ersilia Lucenteforte

Date:

08/04/2019

Submit Form by Email

**Personal data**

Name: Ersilia Lucenteforte

Date and place of birth: 3 November 1979, Venafrò (IS), Italy

Citizenship: Italian

Work address: Department of Clinical and Experimental Medicine, University of Pisa – via Roma 55 - Pisa, Italy

Phone number: +393395849695; e-mail address: ersilia.lucenteforte@unipi.it

**Education**

2012: PhD in Biostatistics, University of Milan

2006: Master in Mathematics Applied to Industry and Services (MAMI), University of Bicocca, Milan

2005: University Degree in Mathematics, University of Perugia, Italy

**Research and Academic Positions**

2018 – to date, Assistant Professor of Biostatistics (MED/01): Department of Clinical and Experimental Medicine, University of Pisa - Research activity: Pharmacoepidemiology

2011 – to date, Collaborator: Diagnostic test accuracy satellite branch of the Cochrane Eyes and Vision Group (DTA@CEVG-IT), University of Florence - Research activity: Systematic review

2017 – 2018, Collaborator: Fondazione GB Bietti for Research in Ophthalmology, Rome - Research activity: Systematic review

2009 – 2018, Senior Research Fellow: Department of Neurosciences, Psychology, Drug Research and Children's Health, University of Florence - Research activity: Pharmacoepidemiology

2006 – 2009, Research Fellow: Department of Epidemiology, Mario Negri Institute for Pharmacological Research, Milan - Research activity: Cancer epidemiology

2008, 2009, Visitor: Genetics and Epidemiology Cluster, Lifestyle, Environment and Cancer Group, International Agency for Research on Cancer, Lyon, France - Research activity: Pooled analysis in the International Pancreatic Cancer Case-Control Consortium (PanC4)

**Awards**

2016, Fellowship: Research Projects on Generic Drugs, funded by Italian Society for Pharmacology (SIF) and "Associazione Nazionale Industrie Farmaci Generici e Biosimilari (Assogenerici)"

2009, Exchange Fellowship: funded by "Environmental Cancer Risk, Nutrition and Individual Susceptibility (ECNIS)"

2008, Exchange Fellowship: funded by "Provincia di Milano"

2005, Fellowship: Post-graduate training in Mathematics Applied to Industry and Services (SAMI), funded by "Istituto Nazionale di Alta Matematica Francesco Severi (INdAM)"

**Memberships**

2017 – to date: Clinical Trial Office of Paediatric University-Hospital Meyer, Florence

2011 – to date: Italian Diagnostic Test Accuracy (DTA) Satellite of the Cochrane Eyes and Vision Group (CEVG)

2010 – to date: Italian Group for Appropriate Drug prescription in the Elderly (I-GrADE)

2010 – to date: Italian Society of Pharmacology

2017: Scientific Board of the "Conferenza di Consenso su Diagnosi e Terapia delle Crisi Psicogene Non Epiletiche", University-Hospital Germaneto, Catanzaro

2017: Scientific Board of the "Conferenza di Consenso su Analgesedazione Procedurale Pediatrica in Pronto Soccorso", University-Hospital Meyer, Florence

2016: Scientific Board of the National meeting "I-GrADE 2016 – Italian Group for Appropriate Drug prescription in the Elderly", Florence

2016: Scientific Board of the "Linee Guida dell'Epilessia in Età Pediatrica"

2008 – 2012: Pancreatic cancer Case-Control Consortium (Panc4)

2006 – 2012: Scientific Board of Working Package Four: Development and assessment of strategic materials for implementation of recommendations for preventing falls among elderly people in the EU", within "The Strategies And Best Practices For The Reduction Of Injuries (APOLLO) Project", funded by European Committee in 2004

**Grants**

2017 – 2018, Principal Investigator: "Safety of Long-acting Nitrates, Ivabradine, Nicorandil and Ranolazine to treat or prevent stable angina: systematic review and meta-analysis", funded by AIFA (FARM12T4BK)

2012 – 2016, Collaborator: "Pharmacological treatment in the elderly patient affected by cardiovascular disease and other chronic comorbidities: inappropriate prescribing and outcome evaluation among institutionalized and community-dwelling elders", funded by AIFA (FARM9LBBBL – Principal Investigator Prof. Alessandro Mugelli)



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### SECTION 1: PERSONAL DETAILS

First Name:	<input type="text" value="Irma"/>
Last Name:	<input type="text" value="Convertino"/>
Organisation / Research Centre :	<input type="text" value="Department of Clinical and Experimental Medicine&lt;br/&gt;Unit of Pharmacology and Pharmacovigilance&lt;br/&gt;University of Pisa"/>
Country:	<input type="text" value="Italy"/>
Contact e-mail Address:	<input type="text" value="convertino.irma@gmail.com"/>

Study Reference Number: EUPAS

Are you the (Primary) Lead Investigator of the above study? No  Yes

Are you an investigator/researcher contributing to the above study No  Yes

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FULL NAME:

Irma Convertino

Date:

08/04/2019

Submit Form by Email

# Irma Convertino Curriculum Vitae

## Personal information

First name / Surname Irma Convertino  
Address Viale delle Cascine 130, Pisa, 56122, Italy  
Mobile +39 3296126848  
E-mail convertino.irma@gmail.com

Nationality *Italian*

## Work experiences

Date	November 2018
Occupation or position held	PhD student
Main activities	“Clinical and translational sciences”
Name and address of employer	Unit of Pharmacology and Pharmacovigilance, Department of Clinical and Experimental Medicine, University of Pisa
Date	From November 2015 to October 2018
Occupation or position held	Research grant
Main activities	“Evaluation of adverse reactions in oncology within the ALEXANDROS study: an intensive monitoring program on the toxicity of biotechnological drugs and target therapies in cancer patients”
Name and address of employer	Unit of Pharmacology and Pharmacovigilance, Department of Clinical and Experimental Medicine, University of Pisa
Date	From November 2013 to November 2015
Occupation or position held	Research fellowship grant
Main activities	“Monitoring of adverse reactions to drugs and vaccines in the North-West Tuscany”
Name and address of employer	Departmental Section of Monitoring Adverse drug reactions, University Hospital of Pisa, Pharmacovigilance Centre of Tuscan North-West Area
Date	From April 2013 to October 2013
Occupation or position held	Continuative collaboration contract
Main activities	“Technology to develop the monitoring of therapies and improve the correct administration of drugs in oncology aiming at ensuring patient safety”
Name and address of employer	Oncological Hospital Pharmacy, IRCCS University Hospital San Martino-IST National Institute for Cancer Research
Date	From May 2011 to March 2013
Occupation or position held	Research fellowship grant
Main activities	“Management of oncological drugs in clinical trials”
Name and address of employer	Oncological Hospital Pharmacy, IRCCS University Hospital San Martino-IST National Institute for Cancer Research, Unità Farmaci Antitumorali, Genova
Date	From May 2010 to November 2010
Occupation or position held	Stage
Main activities	Market access
Name and address of employer	Infosan srl, Milano
Date	From March 2008 to September 2008
Occupation or position held	Internship
Main activities	Hospital Pharmacy
Name and address of employer	University Hospital of Padua, Padua



## Education

Dates	From November 2018
Title of qualification awarded	Ph D. "Clinical and translational sciences"
Name and type of organisation providing education and training	University of Pisa
Dates	From October 2012 to September 2016
Title of qualification awarded	Specialization degree in Hospital Pharmacy (graduation grade 110/110 cum laude, thesis "Neonatal adaptation issues after maternal exposure to prescription drugs: withdrawal syndromes and residual pharmacological effects" at Unit of Pharmacology and Pharmacovigilance of Pisa University and Departmental Section of Monitoring Adverse Drug Reactions of Pisa University Hospital)
Name and type of organisation providing education and training	University of Pisa
Dates	From July 15 <sup>th</sup> to July 26 <sup>th</sup> 2013
Title of qualification awarded	Certification on "the safe use of APOTEC Achemo, the system for the automatic preparation of cytostatic drugs and the use of interfaces to hospital systems to integrate all onco-haematological processes"
Name and type of organisation providing education and training	Loccioni Humancare
Dates	February 2013
Title of qualification awarded	Young European Assessors program
Name and type of organisation providing education and training	Italian Medicines Agency
Dates	From February 2010 to March 2011
Title of qualification awarded	Second level Master degree in pharmaceutical marketing and management (Thesis "Strontium ranelate and the scenario of health regionalization")
Name and type of organisation providing education and training	University of Pavia
Dates	From October 2003 to October 2009
Title of qualification awarded	Degree in Pharmacy (graduation degree 107/110, experimental thesis "New function of cytochrome C exogenous as cardio protective agent in ischemia and myocardial reperfusion", at the Department of Experimental Biomedical Sciences of the University of Padua from September 2008 to October 2009)
Name and type of organisation providing education and training	University of Padua
Dates	From January 2003 to July 2003
Title of qualification awarded	English language certification, level 7
Name and type of organisation providing education and training	Trinity College

## Publications

Ferraro S, Leonardi L, Convertino I, Blandizzi C, Tuccori M. Is There a Risk of Lymphoma Associated With Anti-tumor Necrosis Factor Drugs in Patients With Inflammatory Bowel Disease? A Systematic Review of Observational Studies. *Front Pharmacol.* 2019 Mar 19;10:247. doi: 10.3389/fphar.2019.00247.

Convertino I, Ferraro S, Blandizzi C, Tuccori M. The usefulness of listening social media for pharmacovigilance purposes: a systematic review. *Expert Opin Drug Saf.* 2018 Oct 4:1-13. doi: 10.1080/14740338.2018.1531847

Convertino I, Salvadori S, Pecori A, Galiulo MT, Ferraro S, Parrilli M, Corona T, Turchetti G, Blandizzi C, Tuccori M. Potential Direct Costs of Adverse Drug Events and Possible Cost Savings Achievable by their Prevention in Tuscany, Italy: A Model-Based Analysis. Drug Saf. 2018 Oct 1. doi: 10.1007/s40264-018-0737-0.

Tuccori M, Convertino I, Galiulo MT, Marino A, Capogrosso-Sansone A, Blandizzi C. Diabetes drugs and the incidence of solid cancers: a survey of the current evidence. Expert Opin Drug Saf. 2017 Oct;16(10):1133-1148

Capogrosso Sansone A, Convertino I, Galiulo MT, Salvadori S, Pieroni S, Knezevic T, Mantarro S, Marino A, Hauben M, Blandizzi C, Tuccori M. Muscular Adverse Drug Reactions Associated with Proton Pump Inhibitors: A Disproportionality Analysis Using the Italian National Network of Pharmacovigilance Database. Drug Saf. 2017 Oct;40(10):895-909

Marino A, Capogrosso-Sansone A, Tuccori M, Bini G, Calsolaro V, Mantarro S, Convertino I, Pasqualetti G, Orsitto E, Santini M, Monzani F, Blandizzi C; ANCESTRAL-ED Study Group. Expected and actual adverse drug-drug interactions in elderly patients accessing the emergency department: data from the ANCESTRAL-ED study. Expert Opin Drug Saf. 2016 Dec;15(sup2):45-50

Convertino I., Sansone A.C., Marino A., Galiulo M.T., Mantarro S., Antonioli L., Fornai M., Blandizzi C., Tuccori M. Neonatal Adaptation Issues After Maternal Exposure to Prescription Drugs: Withdrawal Syndromes and Residual Pharmacological Effects. Drug Saf. 2016 Oct;39(10):903-24

Capogrosso Sansone A., Mantarro S., Tuccori M., Ruggiero E., Montagnani S., Convertino I., Marino A., Fornai M., Antonioli L., Corona T., Garibaldi D., Blandizzi C. Safety profile of certolizumab pegol in patients with immune-mediated inflammatory diseases: a systematic review and meta-analysis. Drug Saf. 2015 Oct;38(10):869-88

Mantarro S., Capogrosso Sansone A., Tuccori M., Blandizzi C., Montagnani S., Convertino I., Antonioli L., Fornai M., Cricelli I., Pecchioli S., Cricelli C., Lapi F. Allopurinol adherence among patients with gout: an Italian general practice database study. Int J Clin Pract. 2015 Jul;69(7):757-65

IT skills Good knowledge and use of Microsoft applications (Word, PowerPoint, Excel, Outlook, Access).

I authorize the processing of my personal data according to the Legislative Decree 196/03

Pisa, 08/04/2019

