

Curriculum formative e professionale di Rosa Gini

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Esperienza professionale

- 2011 – attuale* **Responsabile Posizione Organizzativa 'Farmacoepidemiologia'**
Agenzia regionale di sanità della Toscana, Via Dazzi 1, 50141, Firenze
- 2008 - 2011* **Ricercatrice**
Agenzia regionale di sanità della Toscana, Via Dazzi 1, 50141, Firenze
- 2003-2008* **Ricercatrice a contratto**
Agenzia regionale di sanità della Toscana, Via Dazzi 1, 50141, Firenze

Istruzione

- Feb 2011 – Ott 2016* **PhD in Medical Informatics**
Erasmus MC, Department of Medical Informatics
Rotterdam, Paesi Bassi
- Gen 1996 - Apr 2001* **Dottorato in Matematica**
Università di Pisa, Dipartimento di Matematica
Pisa
- Nov 1989-Log 1995* **Laurea in Matematica**
Università degli studi di Milano, Dipartimento di Matematica
Milano

Competenze tecniche e organizzative

- Skills* Data processing (Stata, SQL, R)
Software design e valutazione
- Lingue* Italiano (madrelingua), Inglese, Francese, Spagnolo

Appartenenza a società scientifiche European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (membro eletto dello Steering Group, 2016 – ora; Chair del Working Group sull'indipendenza scientifica e la trasparenza)
International Society of Pharmacoepidemiology (past chair della Taskforce nel Database Special Interest Group)
Associazione Italiana di Epidemiologia (membro eletto dello Steering Group, 2010-2012)

Interessi Framacoepidemiologia, Data Science, Studi di validazione

Tesi di dottorato

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

Responsabile di collana di volumi

2015-2022 *Rapporto sui farmaci in Toscana. Collana ARS Toscana*

Questa collana è stata pubblicata ogni anno dal 2015 al 2022.

Pubblicazioni selezionate

Review e linee guida

Swertz M, Enckevort E van, Oliveira JL, Fortier I, Bergeron J, Thurin NH, et al. Towards an Interoperable Ecosystem of Research Cohort and Real-world Data Catalogues Enabling Multi-center Studies. *Yearb Med Inform.* 2022 Aug;31(1):262–72.

Thurin NH, Pajouheshnia R, Roberto G, Dodd C, Hyeraci G, Bartolini C, et al. From Inception to ConcePTION: Genesis of a Network to Support Better Monitoring and Communication of Medication Safety During Pregnancy and Breastfeeding. *Clin Pharmacol Ther.* 2022 Jan;111(1):321–31. Convertino I, Cazzato M, Giometto S, Gini R, Valdiserra G, Cappello E, et al. Validation of algorithms for selecting rheumatoid arthritis patients in the Tuscan healthcare administrative databases. *Sci Rep.* 2021 Oct 13;11(1):20314.

Sultana J, Crisafulli S, Almas M, Antonazzo IC, Baan E, Bartolini C, et al. Overview of the European post-authorisation study register post-authorization studies performed in Europe from September 2010 to December 2018. *Pharmacoepidemiology and Drug Safety* [Internet]. [cited 2022 Feb 23];n/a(n/a). Available from: <https://onlinelibrary.wiley.com/doi/abs/10.1002/pds.5413>

Spini A, Hyeraci G, Bartolini C, Donnini S, Rosellini P, Gini R, et al. Real-World Utilization of Target- and Immunotherapies for Lung Cancer: A Scoping Review of Studies Based on Routinely Collected Electronic Healthcare Data. *Int J Environ Res Public Health.* 2021 Jul 19;18(14):7679.

Gini R, Sturkenboom MC, Sultana J, Cave A, Landi A, Pacurariu A, et al. *Different strategies to execute multi-database studies for medicines surveillance in real world setting: a reflection on the European model.* *Clinical Pharmacology & Therapeutics.* 2020. Available from: <https://ascpt.onlinelibrary.wiley.com/doi/abs/10.1002/cpt.1833>

Gini R, Fournie X, Dolk H, Kurz X, Verpillat P, Simondon F, et al. *The ENCePP Code of Conduct: A best practice for scientific independence and transparency in non-interventional postauthorisation studies.*

Pharmacoepidemiology and Drug Safety. Available from:
<https://onlinelibrary.wiley.com/doi/abs/10.1002/pds.4763>

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

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.

Data science, methodology and validation studies

Spini A, Rosellini P, Bellan C, Furiesi F, Giorgi S, Donnini S, et al. Development and validation of a case-finding algorithm for the identification of non-small cell lung cancers in a region-wide Italian pathology registry. PLoS One. 2022;17(6):e0269232.

Trifirò G, Isgrò V, Ingrasciotta Y, Ientile V, L'Abbate L, Foti SS, et al. Large-Scale Postmarketing Surveillance of Biological Drugs for Immune-Mediated Inflammatory Diseases Through an Italian Distributed Multi-Database Healthcare Network: The VALORE Project. BioDrugs. 2021 Oct 12;

Gini R, Dodd CN, Bollaerts K, Bartolini C, Roberto G, Huerta-Alvarez C, et al. *Quantifying outcome misclassification in multi-database studies: The case study of pertussis in the ADVANCE project.* Vaccine. 2020 Dec 22;38 Suppl 2:B56–64. ; Available from:
<http://www.sciencedirect.com/science/article/pii/S0264410X19309363>

Hall GC, Lanes S, Bollaerts K, Zhou X, Ferreira G, **Gini R**. *Outcome misclassification: Impact, usual practice in pharmacoepidemiology database studies and an online aid to correct biased estimates of risk ratio or cumulative incidence.* Pharmacoepidemiology and Drug Safety. Available from:
<https://onlinelibrary.wiley.com/doi/abs/10.1002/pds.5109>

Bollaerts K, Rekkas A, Smedt TD, Dodd C, Andrews N, **Gini R**. *Disease misclassification in electronic healthcare database studies: Deriving validity indices—A contribution from the ADVANCE project.* PLOS ONE. 2020 Apr 22;15(4):e0231333.

Bollaerts K, de Smedt T, McGee C, Emborg HD, Villa M, Alexandridou M, et al. ADVANCE: Towards near real-time monitoring of vaccination coverage, benefits and risks using European electronic health record databases. Vaccine. 2020 Dec 22;38:B76–83.

Sturkenboom M, Braeye T, van der Aa L, Danieli G, Dodd C, Duarte-Salles T, et al. ADVANCE database characterisation and fit for purpose assessment for multi-country studies on the coverage, benefits and risks of pertussis vaccinations. Vaccine. 2020 Dec 22;38:B8–21.

Varela LO, Pogam M-AL, Metcalfe A, Kristensen PK, Hider P, Patel A, et al. *Empowering knowledge generation through international data network: the IMeCCHI-DATANETWORK.* International Journal of Population Data Science [Internet]. 2020 Feb 25;5(1). Available from: <https://ijpds.org/article/view/1125>

Almeida JR, **Gini R**, Roberto G, Rijnbeek P, Oliveira JL. *TASKA: A modular task management system to support health research studies.* BMC Med Inform Decis Mak. 2019 Jul 2;19. Available from:
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6604289/>

- 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**
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- Charlton RA, Neville AJ, Jordan S, Pierini A, Damase-Michel C, Klungsoyr 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**

Farmacoepidemiologia

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- Bartolini C, Roberto G, Girardi A, Moscatelli V, Spini A, Barchielli A, et al. *Validity of Italian administrative healthcare data in describing the real-world utilization of infusives antineoplastic drugs: the study case of rituximab use in patients treated at the University Hospital of Siena for onco-haematological indications.* Front Oncol. 2023 May 31;13:1059109.
- Ferraro S, Cappello E, Bartolini C, Convertino I, Bertani L, Lucenteforte E, et al. *Potential missed diagnoses of Crohn's disease in tertiary care: impact on drug utilization and healthcare facilities use.* Eur J Gastroenterol Hepatol. 2023 Sep 18;

- Durán CE, Riera-Arnau J, Abtahi S, Pajouheshnia R, Hoxhaj V, Gamba M, et al. Impact of the 2018 revised Pregnancy Prevention Programme by the European Medicines Agency on the use of oral retinoids in females of childbearing age in Denmark, Italy, Netherlands, and Spain: an interrupted time series analysis. *Front Pharmacol.* 2023;14:1207976.
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- Roberto G, Paoletti O, Ferraro S, Hyeraci G, Franchini M, Gini R, et al. Cases of acquired hemophilia A following COVID-19 vaccines: Cogent safety signal or possible reporting/detection bias? Preliminary evidence from Tuscany, Italy. *Pharmacoepidemiol Drug Saf.* 2023 Mar 17;
- Convertino I, Lorenzoni V, Gini R, Turchetti G, Fini E, Giometto S, et al. Drug-Utilization, Healthcare Facilities Accesses and Costs of the First Generation of JAK Inhibitors in Rheumatoid Arthritis. *Pharmaceuticals.* 2023 Mar;16(3):465.
- Giometto S, Tillati S, Baglietto L, De Bortoli N, Mosca M, Conte M, et al. Use of Biological Drugs for Psoriasis: A Drug-Utilization Study Using Tuscan Administrative Databanks. *Int J Environ Res Public Health.* 2022 Jun 2;19(11):6799.
- Hyeraci G, Gini R, Bezin J, Iannone LF, Benemei S, Lupi C, et al. Utilization patterns, cardiovascular risk, and concomitant serotonergic medications among triptan users between 2008 and 2018: A gender analysis in one Italian region, Tuscany. *Headache: The Journal of Head and Face Pain* [Internet]. [cited 2023 Jan 27];n/a(n/a). Available from: <https://onlinelibrary.wiley.com/doi/abs/10.1111/head.14463>
- Spini A, Giometto S, Donnini S, Posarelli M, Dotta F, Ziche M, et al. Risk of intraocular pressure increase with intravitreal injections of Vascular Endothelial Growth Factor Inhibitors: a cohort study. *American Journal of Ophthalmology* [Internet]. 2022 Nov 17 [cited 2022 Nov 30];0(0). Available from: [https://www.ajo.com/article/S0002-9394\(22\)00440-8/fulltext](https://www.ajo.com/article/S0002-9394(22)00440-8/fulltext)
- Bots SH, Riera-Arnau J, Belitser SV, Messina D, Aragón M, Alsina E, et al. Myocarditis and pericarditis associated with SARS-CoV-2 vaccines: A population-based descriptive cohort and a nested self-controlled risk interval study using electronic health care data from four European countries. *Frontiers in Pharmacology* [Internet]. 2022 [cited 2022 Nov 27];13. Available from: <https://www.frontiersin.org/articles/10.3389/fphar.2022.1038043>
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- Roberto G, Girardi A, Barone-Adesi F, Pecere A, Ientile V, Bartolini C, et al. Time to Treatment Intensification in Patients Receiving DPP4 Inhibitors Versus Sulfonylureas as the First Add-On to Metformin Monotherapy: A Retrospective Cohort Study. *Frontiers in Pharmacology* [Internet]. 2022 [cited 2022 May 30];13. Available from: <https://www.frontiersin.org/article/10.3389/fphar.2022.871052>
- Holthuis E, Smits E, Spentzouris G, Beier D, Enders D, Gini R, et al. Increased Risk of Stroke Due to Non-adherence and Non-persistence with Direct Oral Anticoagulants (DOACs): Real-World Analyses Using a Nested Case-Control Study from The Netherlands, Italy and Germany. *Drugs - Real World Outcomes* [Internet]. 2022 Jul 5 [cited 2022 Jul 6]; Available from: <https://doi.org/10.1007/s40801-022-00317-3>

- Spini A, Crescioli G, Donnini S, Ziche M, Collini F, Gemmi F, et al. Sex differences in the utilization of drugs for COVID-19 treatment among elderly residents in a sample of Italian nursing homes. *Pharmacoepidemiology and Drug Safety* [Internet]. [cited 2022 Feb 23];n/a(n/a). Available from: <https://onlinelibrary.wiley.com/doi/abs/10.1002/pds.5420>
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- Antonazzo IC, Fornari C, Maumus-Robert S, Cei E, Paoletti O, Conti S, et al. Impact of COVID-19 Lockdown, during the Two Waves, on Drug Use and Emergency Department Access in People with Epilepsy: An Interrupted Time-Series Analysis. *International Journal of Environmental Research and Public Health*. 2021 Jan;18(24):13253.
- Trifirò G, Isgrò V, Ingrasciotta Y, Ientile V, L'Abbate L, Foti SS, et al. Large-Scale Postmarketing Surveillance of Biological Drugs for Immune-Mediated Inflammatory Diseases Through an Italian Distributed Multi-Database Healthcare Network: The VALORE Project. *BioDrugs*. 2021 Oct 12;
- Convertino I, Lucenteforte E, Gini R, Lorenzoni V, Cazzato M, Turchetti G, et al. Utilisation Patterns and Clinical Impact of the Introduction of Infliximab-Biosimilar in Tuscany, Italy: Real World Evidence Following the Recommendation of Switching for Non-Medical Reasons. *Clin Exp Rheumatol*. 2020 Aug 5;
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- Spini A, Gini R, Rosellini P, Singier A, Bellan C, Pascucci A, et al. First-Line Pharmacotherapies and Survival among Patients Diagnosed with Non-Resectable NSCLC: A Real-Life Setting Study with Gender Prospective. *Cancers*. 2021 Jan;13(23):6129.
- Giometto S, Baglietto L, Conte M, Vannacci A, Tuccori M, Mugelli A, et al. Use of antiseizure medications and safety of branded versus generic formulations: A comparative study on Tuscan administrative databases. *Epilepsy Behav*. 2021 Apr;117:107876.
- Ingrasciotta Y, Sultana J, Formica D, Ientile V, Aiello A, Chinellato A, et al. Direct healthcare costs of chronic kidney disease management in Italy: What cost-savings can be achieved with higher biosimilar uptake and more appropriate use of erythropoiesis-stimulating agents? *Pharmacoepidemiol Drug Saf*. 2021 Jan;30(1):65-77.
- Antonazzo IC, Fornari C, Paoletti O, Bartolini C, Conti S, Cortesi PA, et al. COVID-19 Outbreak Impact on Anticoagulants Utilization: An Interrupted Time-Series Analysis Using Health Care Administrative Databases. *Thromb Haemost*. 2021 Aug;121(8):1115-8.
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Firenze, 28 September 2021

A handwritten signature in black ink, appearing to be 'Gini R', written in a cursive style.

