



Curriculum Vitae

Personal information **Viviana Giannuzzi**

Work experience

Dates: 07/2010 - Present

Position held: Senior scientist

Employer: Fondazione per la Ricerca Farmacologica Gianni Benzi onlus (Italy)

Main activities in the position: Head of the Research Department.

Senior regulatory manager for consultancy activities: European medicine regulatory procedures, ethical/regulatory support to the preparation of documents for clinical studies (protocol, material for the informed consent and assent process., etc).

Researcher and leader of ethics and regulatory activities/work packages in EU projects.

Project manager of EuOrphan.

Project writer for grant applications.

Dates: 01/2010 - 12/2015

Position held: Consultant

Employer: Consorzio per Valutazioni Biologiche e farmacologiche (Italy)

Main activities in the position: Education and training activities; Regulatory and ethical support to ARPEC project (2009 11 01, Health Programme).

Dates: 04/2010 - 07/2010

Position held: Consultant

Employer: Fondazione per la Ricerca Farmacologica 'Gianni Benzi' onlus (Italy)

Main activities in the position: Scientific Coordination of TEDDY (EU FP6 Network of Excellence LSHB-CT-2005-005216) e-Learning Platform:

preparation/support to the realisation of educational material on paediatric medicines; support to the realisation of the platform.

Dates: 04/2008 - 07/2010

Position held: Scientific Secretary of Ethics Committee

Employer: ASL Lecce (Italy)

Main activities in the position: Support to the evaluation of interventional and non-interventional studies, and the application of current international and national provisions; National Monitoring Centre for Clinical Trials (Osservatorio Nazionale per la Sperimentazione Clinica dei Farmaci) management and data entry.

Dates: 11/2006 - 01/2009

Position held: Post-doctoral position

Employer: University of Bari (Italy)

Main activities in the position: Non-clinical and basic research activity: cytofluorimetric evaluation of calcium homeostasis and calcium channels

activity in physiological and pathological situations including rare diseases (ageing, simulated microgravity, muscular Duchenne dystrophy), in vitro and in vivo therapeutic and toxic effects of drugs; preparation of native muscular fibres from mechanical dissection of rodent muscles; fura-2 imaging technique; Education and training activities in pharmacology, pharmacotherapy and toxicology, drug research, regulatory sciences, paediatric medicines and research.

Education and training

Dates: 12/2008 - 12/2009

Degree or qualification obtained: Post-graduate II level Master in Clinical Research of Medicines

Institution: University of Pisa (Italy)

Subjects/skills covered: Clinical trial methodology, protocol design, enrolment of patients, efficacy and safety evaluation of investigational treatment, rules and procedures on clinical research, role of investigators, patients/subjects information, ethical issues, pharmacogenetic studies, collection of study data, role and tasks of Ethics Committees.

Dates: 10/2003 – 10/2006

Degree or qualification obtained: PhD in Cellular Biochemistry and Cellular Pharmacology

Institution: University of Bari (Italy)

Subjects/skills covered: cytofluorimetric evaluation of calcium homeostasis and calcium channels activity in physiological and pathological situations, in vitro and in vivo therapeutic and toxic effects of drugs; preparation of native muscular fibres from mechanical dissection of rodent muscles; fura-2 imaging technique; pharmacological characterization of native CLC-K renal chloride channels; dissection of rodent kidneys and tubules; patch-clamp technique. Thesis: Muscular disuse and calcium homeostasis: effects of ageing and simulated microgravity on rat slow-twitch and fast-twitch muscle and pharmacological interventions.

Dates: 08/1998 – 07/2003

Degree or qualification obtained: Second level Degree in Pharmacy

Institution: University of Bari (Italy)

Subjects/skills covered: Non clinical research on skeletal muscle calcium homeostasis. Thesis: Effects of a Growth Hormone secretagogue on calcium homeostasis in native rat muscle fibres .

Additional information

Publications

1. Fraysse B., Desaphy J-F., Rolland J.F., Pierno S. Liantonio A., Giannuzzi V., Camerino C., Didonna M.P., Cocchi D., De Luca A., Conte Camerino D.: Fiber type-related changes in rat skeletal muscle calcium homeostasis during aging and restoration by growth hormone *Neurobiology of Disease* 2006; 21(2): 372-80 (ISSN: 0969-9961 (Print); 1095-953X (Electronic)).
2. Liantonio A., Giannuzzi V., Piccolo A., Babini E., Pusch M., Conte Camerino D. Niflumic acid inhibits chloride conductance of rat skeletal muscle by directly inhibiting the CLC-1 channel and by increasing intracellular calcium. *British Journal of Pharmacology* 2007; 150(2): 235-47 (ISSN: 0007-1188 (Print); 1476-5381 (Electronic)).
3. Liantonio A., Giannuzzi V., Cippone V., Camerino G.M., Pierno S., Conte Camerino D.: Fluvastatin and atorvastatin affect calcium homeostasis of rat skeletal muscle fibers in vivo and in vitro by impairing the sarcoplasmic reticulum/mitochondria Ca²⁺-release system. *J. Pharmacol. Exp. Ther.* 2007; 321(2): 626-349 (ISSN: 0022-3565 (Print); 1521-0103 (Electronic)).
4. De Luca A, Nico B, Rolland JF, Cozzoli A, Burdi R, Mangieri D, Giannuzzi V, Liantonio A, Cippone V, De Bellis M, Nicchia GP, Camerino GM, Frigeri A, Svelto M, Camerino DC. Gentamicin treatment in exercised mdx mice: Identification of dystrophin-sensitive pathways and evaluation of efficacy in work-loaded dystrophic muscle. *Neurobiol Dis.* 2008 Nov;32(2):243-53. doi: 10.1016/j.nbd.2008.07.009. Epub 2008 Jul 23. PMID: 18694830.
5. Burdi R, Rolland JF, Fraysse B, Litvinova K, Cozzoli A, Giannuzzi V, Liantonio A, Camerino GM, Sblendorio V, Capogrosso RF, Palmieri B, Andreetta F, Confalonieri P, De Benedictis L, Montagnani M, De Luca A. Multiple pathological events in exercised dystrophic mdx mice are targeted by pentoxifylline: outcome of a large array of in vivo and ex vivo tests. *J Appl Physiol.* 2009; 106: 1311-1324 (ISSN: 0021-8987).
6. A. Liantonio, S. Pierno, C. Digennaro, V. Giannuzzi, G. Gramegna, J-F. Desaphy, D. Conte Camerino The hindlimb unloading model of microgravity differently affects skeletal muscle properties of young and adult mice. *Basic Applied Myology* 19 (2&3): 107-112, 2009 (ISSN: 1120-9992).
7. Desaphy JF, Pierno S, Liantonio A, Giannuzzi V, Digennaro C, Dinardo MM, Camerino GM, Ricciuti P, Brocca L, Pellegrino MA, Bottinelli R, Camerino DC. Antioxidant treatment of hindlimb-unloaded mouse counteracts fiber type transition but not atrophy of disused muscles. *Pharmacol Res.* 2010 Jun;61(6):553-63. doi: 10.1016/j.phrs.2010.01.012. Epub 2010 Jan 29. PMID: 20116431.
8. Liantonio A, Gramegna G, Carbonara G, Sblendorio VT, Pierno S, Fraysse B, Giannuzzi V, Rizzi L, Torsello A, Camerino DC. Growth hormone secretagogues exert differential effects on skeletal muscle calcium homeostasis in male rats depending on the peptidyl/nonpeptidyl structure. *Endocrinology.* 2013 Oct;154(10):3764-75. doi: 10.1210/en.2013-1334. Epub 2013 Jul 8. PMID: 23836033.
9. Ruggieri L, Giannuzzi V, Baiardi P, Bonifazi F, Davies EH, Giaquinto C, Bonifazi D, Felisi M, Chiron C, Pressler R, Rabe H, Whitaker MJ, Neubert A, Jacqz-Aigrain E, Eichler I, Turner MA, Ceci A; GRIP Consortium. Successful private/public funding of paediatric medicines research: lessons from the EU programme to fund research into off-patent medicines. *Eur J Pediatr.* 2015 Apr;174(4):481-91. doi: 10.1007/s00431-014-2398-z. Epub 2014 Sep 23. PMID: 25241827; PMCID: PMC4369287.
10. Cassis L, Cortès-Saladelafont E, Molero-Luis M, Yubero D, González MJ, Ormazábal A, Fons C, Jou C, Sierra C, Castejon Ponce E, Ramos F, Armstrong J, O'Callaghan MM, Casado M, Montero R, Meavilla-Olivas S, Artuch R, Barić I, Bartoloni F, Bellettato CM, Bonifazi F, Ceci A, Cvitanović-Šojat L, Dali CI, D'Avanzo F, Fumic K, Giannuzzi V, Lampe C, Scarpa M, García-Cazorla Á. Review and evaluation of the methodological quality of the existing guidelines and recommendations for inherited neurometabolic disorders. *Orphanet J Rare Dis.* 2015 Dec 30;10:164. doi: 10.1186/s13023-015-0376-9. Erratum in: *Orphanet J Rare Dis.* 2016 Nov 3;11(1):147. PMID: 26714856; PMCID: PMC4696316.
11. Giannuzzi V, Altavilla A, Ruggieri L, Ceci A. Clinical Trial Application in Europe: What Will Change with the New Regulation? *Sci Eng Ethics.* 2016 Apr;22(2):451-66. doi: 10.1007/s11948-015-9662-0. Epub 2015 Jun 3. PMID: 26037896.
12. Conte R, Ruggieri L, Gambino A, Bartoloni F, Baiardi P, Bonifazi D, Bonifazi F, Felisi M, Giannuzzi V, Padula R, Pepe A, Putti MC, Del Vecchio GC, Maggio A, Filosa A, Iacono A, Mangiarini L, Ceci A. The Italian multiregional thalassemia registry: Centers characteristics, services, and patients' population. *Hematology.* 2016 Aug;21(7):415-24. doi: 10.1080/10245332.2015.1101971. Epub 2016 Feb 22. PMID: 26863102.
13. D'Andria P, Giannuzzi V, Bonifazi F, Ceci A, Denora N, Altomare CD. Formulating medicines for children: Challenges and issues. *LA CHIMICA E L'INDUSTRIA.* 2016;3:16-21. DOI:<http://dx.medra.org/10.17374/CI.2016.98.3.4>.
14. Giannuzzi V, Devlieger H, Margari L, Odland VL, Ragab L, Bellettato CM, D'Avanzo F, Lampe C, Cassis L, Cortès-Saladelafont E, Cazorla ÁG, Barić I, Cvitanović-Šojat L, Fumić K, Dali CI, Bartoloni F, Bonifazi F, Scarpa M, Ceci A. The ethical framework for performing research with rare inherited neurometabolic disease patients. *Eur J Pediatr.* 2017 Mar;176(3):395-405. doi: 10.1007/s00431-017-2852-9. Epub 2017 Jan 16. PMID: 28093642; PMCID: PMC5321701.
15. Giannuzzi V, Conte R, Landi A, Ottomano SA, Bonifazi D, Baiardi P, Bonifazi F, Ceci A. Orphan medicinal products in Europe and United States to cover needs of patients with rare diseases: an increased common effort is to be

foreseen. Orphanet J Rare Dis. 2017 Apr 3;12(1):64. doi: 10.1186/s13023-017-0617-1. PMID: 28372595; PMCID: PMC5376695.

16. Neubert A, Baarslag MA, Dijk MV, Rosmalen JV, Standing JF, Sheng Y, Rascher W, Roberts D, Winslade J, Rawcliffe L, Hanning SM, Metsvaht T, Giannuzzi V, Larsson P, Pokorná P, Simonetti A, Tibboel D; CLOSED Consortium. The CLOSED trial; CLONidine compared with midazolam for SEDation of paediatric patients in the intensive care unit: study protocol for a multicentre randomised controlled trial. *BMJ Open*. 2017 Jun 21;7(6):e016031. doi: 10.1136/bmjopen-2017-016031. Erratum in: *BMJ Open*. 2017 Nov 8;7(11):e016031corr1. PMID: 28637741; PMCID: PMC5726127.
17. Giannuzzi V, Landi A, Bosone E, et al Failures to further developing orphan medicinal products after designation granted in Europe: an analysis of marketing authorisation failures and abandoned drugs *BMJ Open* 2017;7:e01735 8. doi: 10.1136/bmjopen-2017-017358.
18. Giannuzzi V, Landi A, Bartoloni F, Ceci A. A Review on Impact of General Data Protection Regulation on Clinical Studies and Informed Consent. *J Clin Res Bioeth* 2018; 9(3):327. doi: 10.4172/2155-9627.1000327.
19. Ceci A, Conte R, Didio A, Bonifazi D, Felisi M, Giannuzzi V, Bonifazi F. An overview of the efficacy and safety of deferiprone in paediatric patients with congenital haemoglobinopathies and chronic iron overload. *Expert Opinion on Orphan Drugs*. 2019; 7:4, 181-197. doi: 10.1080/21678707.2019.1613977.
20. Altavilla A, Hervég J, Giannuzzi V, Landi L, Ceci A. The secondary use of paediatric data under GDPR: looking for new safeguards for research. *EPLR*. 2019; 3(4): 156-164.
21. Landi A, Thompson M, Giannuzzi V, Bonifazi F, Labastida I, Bonino da Silva Santos L.O, Roos M. The "A" of FAIR – As open as possible, as closed as necessary. *Data Intelligence*. 2(2020), 47–55. Doi: 10.1162/dint_a_00027.
22. Bonifazi F, Volpe E, Digregorio G, Giannuzzi V, Ceci A. Machine Learning Systems Applied to Health Data and System. *Eur J Health Law*. 2020 May 19;27(3):242-258. doi: 10.1163/15718093-BJA10009. PMID: 33652397.
23. Toma M, Felisi M, Bonifazi D, Bonifazi F, Giannuzzi V, Reggiardo G, de Wildt S, Ceci A; TEDDY European Network of Excellence for Paediatric Research. Paediatric Medicines in Europe: The Paediatric Regulation-Is It Time for Reform? *Front Med (Lausanne)*. 2021 Feb 2;8:593281. doi: 10.3389/fmed.2021.593281. PMID: 33604345; PMCID: PMC7884470.
24. Giannuzzi V, Felisi M, Bonifazi D, Devlieger H, Papanikolaou G, Ragab L, Fattoum S, Tempesta B, Reggiardo G, Ceci A. Ethical and procedural issues for applying researcher-driven multi-national paediatric clinical trials in and outside the European Union: the challenging experience of the DEEP project. *BMC Med Ethics*. 2021 Apr 29;22(1): 49. doi: 10.1186/s12910-021-00618-2. PMID: 33926431; PMCID: PMC8086274.
25. Altavilla A, Giannuzzi V, Lupo M, Bonifazi D, Ceci A. Ethical, Legal and Regulatory Issues of Paediatric Translational Research. Call for an Adequate Model of Governance. *Eur J Health Law*. 2020 May 18;27(3):213-231. doi: 10.1163/15718093-BJA10010. PMID: 33652400.
26. Kountouris P, Stephanou C, Archer N, Bonifazi F, Giannuzzi V, Kuo KHM, Maggio A, Makani J, Mañú-Pereira MDM, Michailidou K, Nkya S, Nnodu OE, Trompeter S, Tshililo L, Wonkam A, Zilfalil BA, Inusa BPD, Kleanthous M; on behalf of the International Hemoglobinopathy Research Network (INHERENT). The International Hemoglobinopathy Research Network (INHERENT): An international initiative to study the role of genetic modifiers in hemoglobinopathies. *Am J Hematol*. 2021 Nov 1;96(11):E416-E420.
27. Lepola P, Kindred M, Giannuzzi V, Glosli H, Dehlinger-Kremer M, Dalrymple H, Neubauer D, Boylan GB, Conway J, Dewhurst J, Hoffman D. Informed consent and assent guide for paediatric clinical trials in Europe. *Arch Dis Child*. 2021 Dec 1;archdischild-2021-322798. doi: 10.1136/archdischild-2021-322798. Epub ahead of print. PMID: 34853000.
28. Fernández-Luis, S., Lain, M.G., Serna-Pascual, M. et al. Optimizing the World Health Organization algorithm for HIV vertical transmission risk assessment by adding maternal self-reported antiretroviral therapy adherence. *BMC Public Health* 22, 1312 (2022). <https://doi.org/10.1186/s12889-022-13543-9>
29. Giannuzzi V, Stoyanova-Beninska V, Hivert V. Editorial: The use of real world data for regulatory purposes in the rare diseases setting. *Front Pharmacol*. 2022 Nov 24;13:1089033. doi: 10.3389/fphar.2022.1089033. PMID: 36506540; PMCID: PMC9730868.
30. Giannuzzi V, Ruggieri L, Conte R, Manfredi C, Felisi M, Kubiak C, Matei M, Malik S, Demotes J, Ceci A, Bonifazi D. PedCRIN tool for the biosamples management in pediatric clinical trials. *Clin Transl Sci*. 2023 Feb 9. doi: 10.1111/cts.13489. Epub ahead of print. PMID: 36757003.
31. Kerpel-Fronius S, Stoyanova-Beninska V, Giannuzzi V, Sun Z. Editorial: Reviews in: regulatory science. *Front. Med.*, 16 May 2023 Sec. Regulatory Science. Volume 10 - 2023. <https://doi.org/10.3389/fmed.2023.1206757>
32. Ceci A, Conte R, Didio A, Landi A, Ruggieri L, Giannuzzi V, Bonifazi F. Target therapy for high-risk neuroblastoma treatment: integration of regulatory and scientific tools is needed. *Front Med (Lausanne)*. 2023 Jul 14;10:1113460. doi: 10.3389/fmed.2023.1113460. PMID: 37521350; PMCID: PMC10377668.

Projects

Task-force in Europe for Drug Development for the Young (TEDDY)

[31/08/2009 – 30/07/2010]

Scientific co-coordinator of the e-learning platform

FP6-LIFESCIHEALTH

<https://cordis.europa.eu/project/id/5216>

DOI: 10.2165/0148581-200911010-00008

Inherited NeuRoMetabolic Diseases INFORMATION NETWORK (InNerMeD-INETWORK)

[31/03/2013 – 30/09/2015]

leader of the Work Package setting up the platform; researcher, ethical and regulatory expert within the work

package on methodologies (2012 12 12, Second Health Programme 2008-2013)

https://webgate.ec.europa.eu/chafea_pdb/health/projects/20121212/summary

Diferiprone Evaluation in Paediatrics (DEEP)

[31/12/2010 – 30/10/2016]

Coordinating the application of multi-national paediatric clinical studies; ethical and regulatory advice (EU FP7 -

HEALTH-F4-2010-261483); <https://cordis.europa.eu/project/id/261483/it>

Global Research in Paediatrics (GRiP)

[31/12/2010 – 29/06/2017]

e-learning on ethical and regulatory aspects of paediatric research (EU FP7 Network of Excellence - HEALTH-F5-2010-261060); <https://cordis.europa.eu/project/id/261060>.

GAbapentin in Paediatric Pain (GAPP)

[30/06/2013 – 29/06/2017]

ethical and regulatory advice on nonclinical and paediatric clinical studies, support to the coordination of the multi-

national clinical studies, ICH-Good Clinical Practice (GCP) Training Course for investigators (602962 - FP7-HEALTH-2013-INNOVATION-1) <https://cordis.europa.eu/project/id/602962>

Clonidine for Sedation of Paediatric Patients in the Intensive Care Unit (CloSed)
[30/11/2013 – 29/11/2018]

Ethical and regulatory advice and support to the coordination of the paediatric multi-national clinical study preparation and application
(602453 - FP7-HEALTH-2013-INNOVATION-1) <https://cordis.europa.eu/project/id/602453>

Small Medicines Advanced Research Training (SMART)

[31/12/2015 – 30/12/2018]

on-line and face to face training on methodological, ethical and regulatory issues of paediatric trials (692327 - H2020-TWINN-2015) <https://cordis.europa.eu/project/id/692327>
DOI: 10.3030/692327

Paediatric Clinical Research Infrastructure Network (PedCRIN)

[31/12/2016 – 29/06/2021]

Ethical and regulatory expert

<https://cordis.europa.eu/project/id/731046>

DOI: 10.3030/731046

European Paediatric Translational Research Infrastructure (EPTRI)

[31/12/2017 – 29/04/2020]

Ethics Advisory Board member

<https://cordis.europa.eu/project/id/777554>

DOI: 10.3030/777554

conect4children (COllaborative Network for European Clinical Trials For Children)

[30/04/2018 – Current]

Support to regulatory and ethical issues and training on research ethics, Ethics Committees, informed consent and assent in paediatric clinical trials (777389-IMI2-2016-10-04) <https://cordis.europa.eu/project/id/777389>

DOI: 10.3030/777389

European Joint Programme on Rare Diseases (EJP RD)

[31/08/2019 – Current]

Leader of WP on ethics, regulatory and IPR (825575- SC1-BHC-04-2018)

<https://cordis.europa.eu/project/id/825575>

DOI: 10.3030/825575

African Research and Innovative Initiative for Sickle cell Education: Improving Research Capacity for Service Improvement (ARISE)

[31/12/2018 – 31/07/2020]

Leader of Work Package on Ethics requirements (824021-H2020-MSCA-RISE-2018)

<https://cordis.europa.eu/project/id/824021>

DOI: 10.3030/824021

Memberships

since January 2020: Regulatory & Ethics workstream of Global Alliance for Genomics and Health (GA4GH)

since 2018: Working Group on Rare Cancers (WGRC) at ECPC (European Cancer Patient Coalition)

since 2015: EnprEMA working group WG 4 - Ethics

since 2012: Young European AssessorS (YEAS).

since 2008: Member of HTA-Thal Registry Scientific Committee; Ethics and regulatory expert for the Italian Foundation "Leonardo Giambone"

since 2007: Member of the Italian Society of Pharmacology (SIF)

Gruppo di lavoro "Progetto Biobanche" (GdL) crioconservazione di materiale biologico umano set within the Regional Strategic Agency for Health and Society (Agenzia Regionale Strategica per la Salute ed il Sociale - AreSS - Puglia).

Guest (Topic) Editor for FRONTIERS

1- Guest (Topic) Editor for FRONTIERS in Pharmacology - section Drugs Outcomes Research and Policies - for the Research Topic The use of Real World Data for regulatory purposes in the rare diseases setting.

2- 1- Guest (Topic) Editor for FRONTIERS in Medicine for the Research Topic "Reviews in: Regulatory Science".

Other Relevant Information

I am a patient representative