

PERSONAL INFORMATION

Viviana Giannuzzi

WORK EXPERIENCE

August 2010–Present

Researcher

Fondazione per la Ricerca Farmacologica Gianni Benzi onlus (Italy)

Head of Research Department.

Ethical and regulatory expert.

Researcher and leader of Ethics and Regulatory WP in EU projects (see below).

Project manager of EuOrphan.

Project writer for grant applications

Ethical/regulatory support to the preparation of documents for clinical studies including material for the informed consent and assent process.

February 2010–December 2015

Consultant

Consorzio per Valutazioni Biologiche e farmacologiche (Italy)

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

May 2010–July 2010

Consultant

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

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.

May 2008–July 2010

Scientific Secretary of Ethics Committee

ASL Lecce (Italy)

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.

December 2006–January 2009

Post-doctoral position

University of Bari (Italy)

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; pharmacological characterization of native CLC-K renal chloride channels; dissection of rodent kidneys and tubules; patch-clamp technique; Education and training activities in pharmacology, pharmacotherapy and toxicology, drug research, regulatory sciences, paediatric medicines and research.

EDUCATION AND TRAINING

January 2009–December 2009

Post-graduate II level Master in Clinical Research of Medicines

University of Pisa (Italy)

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.

November 2003–October 2006

PhD in Cellular Biochemistry and Cellular Pharmacology

University of Bari (Italy)

Non clinical research on skeletal muscle calcium homeostasis. Thesis: *Muscular disuse and calcium homeostasis: effects of ageing and simulated microgravity on rat slow-twitch and fast-twitch muscle and pharmacological interventions.*

September 1998–July 2003

Second level Degree in Pharmacy

University of Bari (Italy)

Thesis: *Effects of a Growth Hormone secretagogue on calcium homeostasis in native rat muscle fibres.*

ADDITIONAL INFORMATION

Expertise

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., Picollo 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 J-F., Cozzoli A., Burdi R., Mangieri D., Giannuzzi V., Liantonio A., Cippone V., De Bellis M., Nicchia G.P., Camerino G.M., Frigeri A., Svelto M., Camerino D.C. Gentamicin treatment in exercised mdx mice: Identification of dystrophin-sensitive pathways and evaluation of efficacy in work-loaded dystrophic muscle. *Neurobiol Dis.* 2008; 32(2): 243-53 (ISSN: 0969-9961 (Print); 1095-953X (Electronic)).
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 (ISSN: 1043-6618 (Print); 1096-1186 (Electronic)).
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.
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; on behalf of the 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.
10. 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.

11. 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.
12. Cassis L, Cortès-Saladelafont E, Molero-Luis M, Yubero D, González MJ, Herrero AO, Fons C, Jou C, Sierra C, Castejon Ponce E, Ramos F, Armstrong J, O'Callaghan MM, Casado M, Montero R, Olivás SM, 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, Cazorla ÁG. 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(1):164.
13. Giannuzzi V, Devlieger H, Margari L, Odlind VL, Ragab L, Bellettato CM, D'Avanzo F, Lampe C, Schüttler K, Cassis L, Cortès-Saladelafont E, Garcia-Cazorla A, Barić I, Cvitanović-Šojat L, Fumić K, I Dali C, 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.
14. 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.
15. Bonifazi F, Conte R, Baiardi P, Bonifazi D, Felisi M, Giordano P, Giannuzzi V, Iacono A, Padula R, Pepe A, Putti MC, Ruggieri L, Del Vecchio GC, Filosa A, Maggio A, Ceci A; HTA-THAL Multiregional Registry, funded by the Italian Ministry of Health and Fondazione Giambrone. Complications pattern and burden of the disease in patients affected by beta-thalassaemia major. *1.Curr Med Res Opin*. 2017 Aug;33(8):1525-1533. doi: 10.1080/03007995.2017.1326890.
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, Pokorný P, Simonetti A, Tibboel D; CLOSED Consortium. The CLOSED- trial; CLONidine compared to 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.
17. Giannuzzi V, Landi A, Bosone E, Giannuzzi F, Nicotri S, Torrent-Farnell J, Bonifazi F, Felisi M, Bonifazi D, Ceci A. Failures to further developing orphan medicinal products after designation granted in Europe: an analysis of marketing authorisation failures and abandoned drugs. *BMJ Open*. 2017 Sep 11;7(9):e017358. 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

Projects

- DEEP (EU FP7 - HEALTH-F4-2010-261483): ethical and regulatory advice on paediatric clinical studies;
- GRiP (EU FP7 Network of Excellence - HEALTH-F5-2010-261060);
- CloSed (602453 - FP7-HEALTH-2013-INNOVATION-1): ethical and regulatory advice on paediatric clinical study;
- GAPP (602962 - FP7-HEALTH-2013-INNOVATION-1): ethical and regulatory advice on nonclinical and paediatric clinical studies;
- InNerMeD-INETWORK (2012 12 12, Second Health Programme 2008-2013): leader of WP on IT platform;
- SMART (692327 - H2020-TWINN-2015): ethical and regulatory advice on paediatric research;
- Early treated Perinatally HIV Infected individuals: Improving Children's Actual Life (EPIICAL) - Viiv Healthcare grant: leader of WP on ethics and regulatory;
- ARISE (824021-H2020-MSCA-RISE-2018): Leader of WP on ethics.
- EJP-RD - European Joint Programme on Rare Diseases (825575- SC1-BHC-04-2018): Leader of WP on ethics, regulatory and IPR.

Memberships

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

Other Relevant Information