



Curriculum Vitae

Personal information **Francesca Luciani**

Work experience

1. Employer: Istituto Superiore di Sanità
 - Start date: 091998
 - End date: 122003
 - Position: Researcher
 - Activities: Research activity aimed at identifying new tumor antigens and protein interaction mechanisms involved in scaffolding and signal transduction both in immune and in tumor cells (lymphocytes, monocytes, NK cells, lymphoblastoid and monoblastoid cell lines, primary and metastatic melanoma cell lines). Studying the role of the cytoskeleton in the regulation of Fas (CD95)-mediated apoptosis and of Pgp-1 mediated multidrug resistance (MDR). Studying the lysosomal apparatus dynamics and its involvement in drug sequestering, in order to identify new therapeutic approaches able to improve anti-cancer drug efficacy.
 - Country: Italy
2. Employer: Istituto Superiore di Sanità
 - Start date: 012004
 - End date: 022007
 - Position: Researcher
 - Activities: Biologicals control and evaluation, batch release and plasma pool testing activities, in compliance with the PhEur and Italian government directives. Research activity concerning new infectious emergencies potentially affecting the quality of human blood derived biologics (i.e. B19 Parvovirus, West Nile virus) and the development of more reliable, specific and sensible test methods to detect such infectious agents
 - Country: Italy
3. Employer: European Medicines Agency
 - Start date: 032007
 - End date: 022008
 - Position: Scientific Administrator
 - Activities: Scientific administrator in the Safety and Efficacy Sector in the Pre-Authorization Human Unit. Member of the anti-infectives therapeutic group. Responsible for handling the safety and efficacy part of new centralized applications and referral procedures mainly related to anti-infectives, immunology, vaccines, gastroenterology, musculoskeletal and rheumatology. Collaboration to the EMEA "Bioterrorism" project.
 - Country: United Kingdom
4. Employer: Istituto Superiore di Sanità
 - Start date: 032008
 - End date: 042018
 - Position: Researcher
 - Activities: Biologicals control and evaluation, batch release and plasma pool testing activities, in compliance with the PhEur and Italian government directives. Responsible for the set up of biological assays to evaluate the potency of monoclonal antibodies and peptides derived from recombinant DNA technology and intended for clinical use. This activity is performed in the context of CAP (Centrally Authorized Products) Programme Surveillance Activity organized and planned yearly by EDQM. Participation in Biological Standardization Programme (BSP) for the establishment of new reference standards and the development of new/alternative test methods, in the context of PhEur activity. Research activity concerning new infectious emergencies potentially affecting the quality of human blood derived biologics (i.e. B19 Parvovirus, West Nile virus) and the development of more reliable, specific and sensible test methods to detect such infectious agents. Quality and non-clinical assessor for centralized, decentralized and mutual recognition procedures regarding biological drugs, such as blood derived products, heparins, urine-derived products and biologicals produced by rDNA technology. Quality assessor for biological Investigational medicinal products (IMP) to be submitted to Phase I clinical trials. European Expert nominated by the Italian Medicines agency participating to the peer review system and to working and drafting groups of the European Medicines Agency. Expert of the Biotech working party (BWP) of the European Medicines Agency.
 - Country: Italy
5. Employer: ISS/AIFA
 - Start date: 052016
 - End date: 112020
 - Position: Italian Alternate at the CHMP Biologics Working Party (BWP)
 - Activities: Active participation to the activities of the BWP, including assessment of module 3 for MAA for Biotech products, Scientific advice for quality questions on Biotech products, drafting groups and other relevant activities.
 - Country: Italy
6. Employer: Istituto Superiore di Sanità
 - Start date: 052018
 - End date:
 - Position: Head of the Biotech Products Section, CNCF
 - Activities: Head of the Biotech Products Section, in the Biologicals Unit of the National center for the Control and evaluation of Medicines. Responsible for the set up of biological assays to evaluate the potency of monoclonal antibodies and peptides derived from recombinant DNA technology and intended for clinical use. This activity is performed in the context of CAP (Centrally Authorized Products) testing and sampling Programme organized and planned yearly by EDQM. Research activity to develop new biological assays to test the identity and potency of biotech products. Participation in Biological Standardization Programme (BSP) for the

establishment of new reference standards and the development of new/alternative test methods, in the context of PHEUR activity. Participation to WHO collaborative studies for the standardization of IS for monoclonal antibodies. Biologicals control and evaluation , batch release an plasma pool testing activities, in compliance with the PHEUR and Italian government directives. Quality assessor for centralized, decentralized and mutual recognition procedures regarding biological drugs, such as blood derived products, heparins, urine_derived products and Biotech products. Quality assessor for Biotech Investigational medicinal products (IMP) to be submitted to Phase I clinical trials. European Expert nominated by the Italian Medicines agency participating to the peer review system and to working and drafting groups of the European Medicines Agency. Expert of the Biotech working party (BWP) of the European Medicines Agency.

- Country: Italy
- 7. Employer: ISS
 - Start date: 102018
 - End date:
 - Position: Expert member of the OMCL MAB testing working group at EDQM.
 - Activities: Participation to the activities of the group aimed at developing approaches for the independent testing of monoclonal antibodies, in the context of surveillance and anti_counterfeit activities.
 - Country: Italy
- 8. Employer: ISS
 - Start date: 062019
 - End date:
 - Position: Expert member of the MAB Working Party at EDQM
 - Activities: Participation to the activities of the MAB working parti at EDQM, including drafting of Ph.Eur. texts, participation in collaborative studies for the standardization of reference materials and analytical methods for monoclonal antibodies for therapeutic use.
 - Country: Italy
- 9. Employer: ISS
 - Start date: 112020
 - End date:
 - Position: Expert member of the P4Bio Working Party at EDQM
 - Activities: Participation to the activities of the P4Bioworking parti at EDQM, including drafting of Ph.Eur. texts, participation in collaborative studies for the standardization of analytical methods for biological medicines for therapeutic use.
 - Country: Italy
- 10. Employer: ISS/AIFA
 - Start date: 122020
 - End date:
 - Position: Italian member of the CHMP Biologics Working Party
 - Activities: Active participation to the activities of the BWP, including coordination of assessment of module 3 for MAA for Biotech products, Scientific advice for quality questions on Biotech products, drafting groups and other relevant activities.
 - Country: Italy

Education and training

- 1. Subject: Università degli Studi
 - Start date: 111991
 - End date: 031998
 - Qualification: Degree in Biological Sciences (BSc, Specialized in Biotechnology)
 - Organisation: Experimental thesis: Study on the effects of the constitutive expression of the HIV_1 protein Vpr in a T_cell line. Implications for AIDS pathogenesis. Skills: virology (virus culture and interferon titration), molecular biology (DNA cloning, PCR, Southern/Northern blotting) and cellular biology (cell cultures, citochemistry) techniques. Assistant researcher in identifying the role of Interferons in the regulation of the P glycoprotein (Pgp1) involved in the Multi Drug Resistance (MDR).
 - Country: Italy

Additional information

Publications

1. Patrizia Puddu, Stefano Fais, Francesca Luciani, Giovanni Gherardi, MariaLuisa Dupuis, Giulia Romagnoli, Maurizio Cianfriglia and Sandra Gessani: "Interferon- α upregulates expression and activity of P_glycoprotein in human peripheral blood monocyte_derived macrophages"; Laboratory Investigation (1999), 79 (10): 1299_1309. (I.F. 4.418)
2. Stefano Fais, Francesca Luciani, Mariantonia Logozzi, Stefania Parlato and Francesco Lozupone: "Linkage between cell membrane proteins and actin_based cytoskeleton: the cytoskeletal_driven cellular functions" Histology and Histopathology (2000), 15: 539_549. (I.F. 1.830)
3. Francesco Lozupone, Francesca Luciani, Massimo Venditti, Licia Rivoltini, Serenella Pupa, Giorgio Parmiani, Filippo Belardelli and Stefano Fais "Murine granulocytes control human tumor growth in scid mice" International Journal of Cancer (2000), 87: 569_573. (I.F. 4.375)
4. Stefania Parlato, Annamaria Giammaroli, Mariantonia Logozzi, Francesco Lozupone, Paola Matarrese, Francesca Luciani, Mario Falchi, Walter Malorni and Stefano Fais: "CD95 (APO_1/FAS) linkage to the actin cytoskeleton: a novel regulatory mechanism of the CD95 apoptotic pathway"; EMBO Journal (2000), EMBO Journal (2000), 19: 5123_5134. (I.F. 10.456)
5. Francesca Luciani, Agnese Molinari, Francesco Lozupone, Annarica Calcabrini, Luana Lugini, Annarita Stringaro, Patrizia Puddu, Giuseppe Arancia, Maurizio Cianfriglia and Stefano Fais: "P_glycoprotein/actin association through ERM family proteins: a role in P_glycoprotein function in human cells of lymphoid origin"; Blood (2002), 99: 641_648. (I.F. 10.120)
6. Carlo Ramoni, Francesca Luciani, Francesca Spadaro, Luana Lugini, Francesco Lozupone and Stefano Fais. Differential expression and distribution of ezrin, radixin and moesin in human natural killer cells. European Journal of Immunology (2002), 32:3059_3065. (I.F. 4.536)
7. Francesco Lozupone, Licia Rivoltini, Francesca Luciani, Massimo Venditti, Luana Lugini, Agata Cova, Paola Squarcina, Giorgio Parmiani, Filippo Belardelli and Stefano Fais. Adoptive transfer of an anti_MART_1(27_35)_specific CD8+ T cell clone leads to immunoselection of human melanoma antigen_loss variants in SCID mice. European Journal of Immunology (2003), 33:556_66. (I.F. 4.536)
8. Luana Lugini, Francesco Lozupone, Paola Matarrese, Cristina Funaro, Francesca Luciani, Walter Malorni, Licia Rivoltini, Chiara Castelli, Antonella Tinari, Adriano Piris, Giorgio Parmiani, and Stefano Fais: "Potent phagocytic activity discriminates metastatic and primary human malignant melanomas: a key role of ezrin". Laboratory Investigation 2003 Nov; 83(11):1555_1567. (I.F. 4.418)
9. Francesco Lozupone, Luana Lugini, Paola Matarrese, Francesca Luciani, Cristina Federici, Elisabetta Iessi, Paola Margutti, Giorgio Stassi, Walter Malorni and Stefano Fais. Identification and relevance of the CD95_binding domain in the N_terminal region of Ezrin. J.Biol Chem. 2004;279(10):9199_9207. (I.F. 6.696)
10. Francesco Lozupone, Daniela Pende, Vito Burgio, Chiara Castelli, Massimo Spada, Massimo Venditti, Francesca Luciani, Luana Lugini, Cristina Federici, Carlo Ramoni, Licia Rivoltini, Giorgio Parmiani, Filippo Belardelli, P. Rivera, S. Marcenaro, Lorenzo Moretta and Stefano Fais. Effect of human NK and gamma/delta T cells on the growth of human autologous melanoma xenografts in SCID mice. Cancer Research, 2004;64(1):378_385. (I.F. 8.649)
11. Francesca Luciani, Paola Matarrese, Anna Maria Giammaroli, Luana Lugini, Francesco Lozupone, Cristina Federici, Elisabetta Iessi, Walter Malorni and Stefano Fais. CD95/phosphorylated ezrin association underlies HIV_1 gp120/IL_2 induced susceptibility to CD95(APO_1/Fas)_mediated apoptosis of human resting CD4+_T lymphocytes. Cell Death and Differentiation, 2004;11(5):574_82. (I.F. 7.008)
12. Francesca Luciani, Massimo Spada, Angelo De Milito, Agnese Molinari, Licia Rivoltini, Annalisa Montanaro, Manuela Marra, Luana Lugini, Mariantonia Logozzi, Francesco Lozupone,

Cristina Federici, Lisa Iessi, Giorgio Parmiani, Giuseppe Arancia, Filippo Belardelli and Stefano Fais. Effect of proton pump inhibitor pretreatment on resistance of solid tumors to cytotoxic drugs. *Journal of National Cancer Institute*, 2004; 96(22):1702_1713. (I.F. 13.844) 13. Luana Lugini, Paola Matarrese, Antonella Tinari, Francesco Lozupone, Cristina Federici, Elisabetta Iessi, Massimo Gentile, Francesca Luciani, Giorgio Parmiani, Licia Rivoltini, Walter Malori and Stefano Fais. Cannibalism of live lymphocytes by human metastatic but not primary melanoma cells. *Cancer Research* (2006); 66(7): 3629_3638. 14. Francesca Luciani in: Susan J. Thorpe, Bernard Fox, Alan Heath, Marie Emmanuelle Behr Gross, Maria L. Virata and Mei Ying W. Yu. International collaborative study to assess candidate reference preparations to control the level of anti_D in IVIG for use in Europe and in the United States. *Biologicals*, 2006; 34:209_212. 15. Giulio Pisani, Francesco Marino, Karen Cristiano, Guillermo M Bisso, Claudio Mele, Francesca Luciani, Maria Wirz, Giuliano Gentili; the External Quality Assessment Participants. External quality assessment for the detection of HCV RNA, HIV RNA and HBV DNA in plasma by nucleic acid amplification technology: a novel approach. *Vox Sanguinis*. 2008 Mar 31, Epub ahead of print. 16. Giulio Pisani, Francesco Marino, Karen Cristiano, Guillermo M Bisso, Claudio Mele, Francesca Luciani, Maria Wirz, Giuliano Gentili; National Collaborative Study Group. Collaborative study for the calibration of HCV RNA, HBV DNA and HIV RNA reference preparations against the relative international standards. *Annali Istituto Superiore Sanita'*. 2007; 43(1):69_76. 17. Giulio Pisani, Francesco Marino, Karen Cristiano, Guillermo M Bisso, Claudio Mele, Francesca Luciani, Maria Wirz, Giuliano Gentili; External Quality Assessment Participants. External quality assessment for the detection of HCV RNA, HIV RNA and HBV DNA in plasma by nucleic acid amplification technology: a novel approach. *Vox Sang*. 2008 Jul;95(1):8_12. 18. Pisani G, Cristiano K, Marino F, Luciani F, Bisso GM, Mele C, Adriani D, Piccinini V, Colombo K, Marra C, Pini C and Grazzini G. Programma italiano di Valutazione Esterna di Qualità per le tecniche di amplificazione genomica (NAT) HCV RNA, HIV RNA, HBV DNA. Anno 2008. *Blood Transfusion* 2009;7 supplement 2: May, pag s72 21. Pisani G, Pupella S, Marino F, Cristiano K, Luciani F, Bisso GM, Gaggioli A, Mele C, Adriani D, Colombo K, Marra C, Wirz M., Vitalli S, Piccinini V, Grazzini G. Programma di Valutazione Esterna di Qualità per le tecniche NAT impiegate per la qualificazione biologica dei prodotti ad uso trasfusionale. Esperienza italiana nel biennio 2008_2009. *Blood Transf* (2010) 8 (suppl 2): 37_39. 22. Pisani G, Cristiano K, Marino F, Luciani F, Bisso GM, Gaggioli A, Mele C, Pupella S, Grazzini G, and Wirz M. External Quality Assessment Programmes For Detection Of HCV RNA, HIV RNA and HBV DNA in Plasma: Improved Proficiency of the Participants Observed Over a Two Year Period. *Vox Sanguinis* (2010).99(4):319_324. 23. Dell'Omo P, Luciani F and Malagutti L. Trattamento HYST delle biomasse: risultati per l'alimentazione animale e le bioenergie. *Tecnica Molitoria* (2011) anno 62, n.7, pp 708_715. 24. Luciani F, Daas A and Terao E: Collaborative Study for the establishment of the Ph.Eur hepatitis B Immunoglobulin Biological Reference Preparation (BRP) Phase I Report (BSP103). EDQM document n. PA/PH/BIO (11) 16: 1_26 25. Pisani G, Pupella S, Cristiano K, Marino F, Simeoni M, Luciani F, Scuderi G, Sambri V, Rossini G, Gaibani P, Piarro A, Wirz M, Grazzini G. Detection of West Nile virus RNA (lineages 1 and 2) in an external quality assessment programme for laboratories screening blood and blood components for West Nile virus by nucleic acid amplification testing. *Blood Transf*. 2012 Oct;10(4):515_20 26. Lugini L, Cecchetti S, Huber V, Luciani F, Macchia G, Spadaro F, Paris L, Abalsamo L, Colone M, Molinari A, Podo F, Rivoltini L, Ramoni C, Fais S. Immune surveillance properties of human NK cell derived exosomes. *J. Immunol*. 2012 Sep 15;189(6):2833_42 27. Thelwel C, Rigsby P, Longstaff C; ISTH_SSC Subcommittee on Factor XI and Contact System. (Breitner_Ruddock S, Zander N, Michalski C, Linstead S, Blessing H, Kerbl B, Wouters D, Nieuwenhuys E, Abbink_Wiersum K, Gartner P, Varga L, Zadro R, Cicardi M, Langer E, Karnaukhova E, Lopez_Trascasa M, Nozal P, Drouet C, Regenass S, Nielson E, Marzsal E, Wirz M, Luciani F, Thelwell C, Whitfield P, Egner W, Dengler K, Masselou K, Plant T, Korte W, Roux_Lombard P, Aygoeren E, Kreuz W.) An international collaborative study to establish the WHO 1st international standards for C1_inhibitor, plasma and concentrate. *J Thromb Haemost*. 2011 Oct;9(10):2097_9 28. Luciani F, Galluzzo G., Gaggioli A., Aaby_Kruse N., Vennegues P., Schneider CK., Pnin C., Melchiorri D. "Implementing quality by design for biotech products: are regulators on track?" 2015 *mAbs* 7(3):451_455. 29. Esposito V., Luciani F., Battistone A., von Hunolstein C., Marino F. "Development of a new, simple, rapid ultra_high_performance liquid chromatography (UHPLC) method for the quantification of 2-phenoxyethanol in vaccines for human use" 2021. *Biologicals* 69: 15-21

Projects

Memberships

Invitation as a speaker to the PDA 8th workshop on Monoclonal Antibodies, Presentation: "Specification setting and statistic tools: regulatory considerations" 22 September 2015, Berlin. Co_chair of the PDA 9th workshop on Monoclonal Antibodies, 20_21 September 2016, Invitation as a speaker to the CASSS WCBP 2019 conference. Presentation: "Summary EMA activities: Biosimilarity" ...January 2019 Washington DC Invitation as a speaker to the CASSS Bioassays 2019 conference. Presentation: "Bioassays: the Italian OMCL experience", May 2019 Washington DC

Other Relevant Information