



Curriculum Vitae

Personal information **Sara Galluzzo**

Work experience

Bambino Gesù' Research Hospital (OPBG IRCCS)

- Start date: 092024 (on temporary leave from AIFA)
- End date:
- Position: Head of Technology Transfer Office, Scientific Directorate
- Activities: management of OPBG intellectual property (IP) assets and the transfer of knowledge and technology to industry; steering translational research projects through the technology transfer cycle. Promotion of relations between OPBG and stakeholders including Universities/research centers and Industry by increasing the possibilities for clinical and industrial application of innovative scientific research.

EMA

- Start date: 042020
- End date: 062024
- Position: Member of the European Task Force (ETF)
- Activities: Support to the Agency for COVID_19 related activities (scientific advice, clinical trials, discussion of MAA) and any other emergency in EU.
- Country: Netherland

EMA

- Start date: 022020
- End date:
- Position: Member of Scientific advice working party nominated by PDCO
- Activities: Scientific advice for medicinal products for human use to facilitate timely access of safe and efficacious medicinal products to patients by optimising research and development, by reducing uncertainties in regulatory outcomes. Specifically acting as liaison between SAWP and PDCO with the aim of harmonize the outcome of the two procedures.
- Country: Netherlands

EMA

- Start date: 072016
- End date:
- Position: Italian member at Paediatric Committee (PDCO)
- Activities: Acting as a member of the PDCO by providing scientific expertise, including assessment of pediatric investigation plans, and defining paediatric needs. Specific expertise in the immunology and immunotherapies, IBD, reumatology, liver and metabolic diseases, rare diseases.
- Country: Netherlands

1. Employer: Agenzia Italiana del Farmaco (AIFA), Rome (Italy)

- Start date: 112010
- End date: 092024
- Position: Senior clinical assessor and PTL
- Activities: At AIFA (Innovation and Pharmaceutical Strategy Division): _ Evaluation of centralized procedures, IT acting as (Co_)Rapporteur at CHMP: product team leader and senior clinical assessor (efficacy and safety) of medicinal products in the fields of i) immuno_inflammatory diseases: immunology/rheumatology, gastrointestinal (IBD); ii) oncology and immunotherapies; iii) diagnostic tests/biomarkers selection and evaluation/molecular platforms/innovative study designs; iv) biosimilars _Assessment of national scientific advices related to the described fields; _ Evaluation of national dossiers in support of HTA activities (CTS and CPR commissions) ; _ Evaluation of clinical trials (phase IIb, III, IV) in support of Clinical Trials Office activity; _Former Aifa Observer at the Fase I Commission (National Institute of Health) for evaluation of phase I trials; _Support to Horizon Scanning activities and prioritization of drugs; At EMA: _ Scientific support to IT CHMP members; _ Assessment of EU scientific advices and parallel EMA/HTA related to the described fields; _ Former member of the Immunology and Rheumatology working group (2010_2017); _Observer of the Infectious diseases working group;
- Country: Italy

2. Employer: Medical Oncology Dept., University Campus Bio_Medico, Rome (Italy)

- Start date: 052006
- End date: 112010
- Position: Medical Doctor, senior research fellow and lecturer
- Activities: Medical and Academic: _Responsible of the Oncology Translational Laboratory (predictive/prognostic biomarkers; immuno_oncology); _Study coordinator of clinical trials (phase II and phase III) of the Oncology Dept. _Teaching activity (Immunology and General Pathology classes)
- Country: Italy

3. Employer: Clinical Immunology Dept. University Campus Bio_Medico, Rome (Italy)

- Start date: 042005

- End date: 052006
- Position: Medical Doctor, research fellow
- Activities: Medical and Academic: _clinical activity in and out patient, focused on diagnosis and treatment of autoimmune and rheumatic diseases; _teaching activity (Immunology and Rheumatology classes) _clinical translational research focused on autoimmunity
- Country: Italy

Education and training

1. Subject: Catholic University "del Sacro Cuore" of Rome, Italy
 - Start date: 112009
 - End date: 112010
 - Qualification: M.A. advanced level
 - Organisation: Pre_clinical and clinical research and development of drugs: technical, scientific, regulatory and ethical aspects.
 - Country: Italy
2. Subject: Columbia University, New York (USA) Dept of Pathology, Immunology and Immunogenetics laboratory (2004_2005) and University Campus Bio_Medico, Rome (Italy) Dept Medical Oncology, Translational Oncology Lab. (2006_2007).
 - Start date: 112004
 - End date: 112007
 - Qualification: PhD
 - Organisation: Experimental Oncology Tumor Immunology Cellular and molecular biology
 - Country: United States
3. Subject: Italian Minister of University and Research (MIUR)
 - Start date: 092005
 - End date: 092006
 - Qualification: M.A.
 - Organisation: _Approaches of clinical tutoring in the Faculty of Medicine _Problem Based Learning model
 - Country: Italy
4. Subject: Columbia University, New York (USA) Dept. of Pathology, Immunology and Immunogenetics laboratory
 - Start date: 072003
 - End date: 032005
 - Qualification: Post Doctoral Research fellow
 - Organisation: _ research activity in immunology and immunogenetics (transplant immunology) _cellular and molecular biology techniques
 - Country: United States
5. Subject: University "La Sapienza", Rome (Italy), Fellowship in Internal Medicine (Clinical Immunology oriented). From July 2003 at Columbia University, New York (USA)
 - Start date: 111999
 - End date: 112004
 - Qualification: Specialist in Internal Medicine (Clinical Immunology).
 - Organisation: _ clinical practice (in and out patient) _ translational research activity in clinical immunology
 - Country: Italy
6. Subject: Italian Minister of University and Research (MIUR)
 - Start date: 112001
 - End date: 112002
 - Qualification: M.A.
 - Organisation: Clinical Tutoring: _communication, teaching and learning skills _problem solving approach applied to students
 - Country: Italy
7. Subject: University Campus Bio_Medico, Rome (Italy)
 - Start date: 091993
 - End date: 071999
 - Qualification: Medical degree
 - Organisation: Thesis dissertation: Clinical immunology, autoimmunity Graduated magna cum laude.
 - Country: Italy

Additional information

Publications

Co-author of 49 papers on International peer reviewed journals Karres D, Lesa G, Ligas F, Benchetrit S, Galluzzo S, Van Malderen K, Sterba J, van Dartel M, Renard M, Sisovsky P, Wang S, Norga K. European regulatory strategy for supporting childhood cancer therapy developments. *Eur J Cancer.* 2022 Dec;177:25_29. Pearson ADJ, Rossig C, Lesa G, Diede SJ, Weiner S, Anderson J, Gray J, Geoerger B, Minard_Colin V, Marshall LV, Smith M, Sondel P, Bajars M, Baldazzi C, Barry E, Blackman S, Blanc P, Capdeville R, Caron H, Cole PD, Jiménez JC, Demolis P, Donoghue M, Elgadi M, Gajewski T, Galluzzo S, et al. ACCELERATE and European Medicines Agency Paediatric Strategy Forum for medicinal product development of checkpoint inhibitors for use in combination therapy in paediatric patients. *Eur J Cancer.* 2020 Mar;127:52_66 Luciani F, Galluzzo S (Co_first author), Gaggioli A, Aaby Kruse N, Venneugues P, Schneider CK, Pini C, Melchiorri D. Implementing quality by design for biotech products: are regulators on track? *MAbs.* 2015;7(3):451_5 Boix_Perales H, Borregaard J, Jensen KB, Erbsøll J, Galluzzo S, Giuliani R, Ciceroni C, Melchiorri D, Salmonson T, Bergh J, Schellens JH, Pignatti F. The European Medicines Agency Review of Pertuzumab for the treatment of adult patients with HER2_positive metastatic or locally recurrent unresectable breast cancer: summary of the scientific assessment of the committee for medicinal products for human use. *Oncologist.* 2014 Jul;19(7):766_73 Angeletti S, Gherardi G, De Florio L, Avola A, Crea F, Riva E, Vitali MA, Galluzzo S, Dicuonzo G. Real_time polymerase chain reaction with melting analysis of positive blood culture specimens in bloodstream infections: diagnostic value and turnaround time. *New Microbiol.* 2013 Jan;36(1):65_74. Galluzzo S, Patti G, Dicuonzo G, Di Sciascio G, Tonini G, Ferraro E, Spoto C, Campanale R and Angeletti S. Association between NOD2/CARD15 polymorphisms and coronary artery disease: a prospective, case_control study. *Hum Immunol.* 2011 Aug;72(8):636_40. D Santini, B Vincenzi, V Adamo, R Addeo, V Fusco A Russo, F Montemurro, I Roato, S Redana, G Lanzetta, MA Satolli, A Berruti, V Leoni, Galluzzo S, M Antimi, G Ferraro, M Rossi, S Del Prete, MR Valerio, M Caraglia and G Tonini Cigarettes smoking habit does not reduce benefit from first line trastuzumab_based treatment in advanced breast cancer patients *Oncol Rep.* 2011 Mar 28. B Vincenzi, G Perrone, S Galluzzo, A Frezza, D Santini, A Zoccoli, G Tonini PML As A Potential Predictive Factor Of Efficacy Of Oxaliplatin Based First Line Chemotherapy In Colorectal Cancer Patients. *J Cell Physiol.* 2011 Apr 18. Santini D, Schiavon G, Vincenzi B, Gaeta L, Pantano F, Russo A, Ortega C, Porta C, Galluzzo S, Armento G, La Verde N, Caroti C, Treilleux I, Ruggiero A, Perrone G, Addeo R, Clezardin P, Onetti Muda A, Tonini G. Receptor activator of NF_kB (RANK) expression associates with bone metastasis occurrence in breast cancer patients. *PLoS One.* 2011 Apr 29;6(4):e19234. Santini D, Galluzzo S, Gaeta L, Zoccoli A, Riva E, Ruzzo A, Vincenzi B, Graziano F, Loupakis F, Falcone A, Muda AO, Tonini G. Should Oncologists Be Aware in Their Clinical Practice of KRAS Molecular Analysis? *J Clin Oncol.* 2011 Jan 24. Fratto ME, Santini D, Vincenzi B, Silvestris N, Azzariti A, Tommasi S, Zoccoli A, Galluzzo S, Maiello E, Colucci G, Tonini G. Targeting EGFR

in bilio-pancreatic and liver carcinoma. *Front Biosci (Schol Ed)*. 2011 Jan 1;3:16_22. Santini D, Fratto ME, Spoto C, Galluzzo S, Zoccoli A, Vincenzi B, Tonini G. Cetuximab in small bowel adenocarcinoma (SBA): a new friend? *Br J Cancer*. 2010 Oct 12; 103 (8):1305. Santini D, Galluzzo S, Zoccoli A, Pantano F, Fratto ME, Vincenzi B, Lombardi L, Gucciardino C, Silvestris N, Riva E, Rizzo S, Russo A, Maiello E, Colucci G, Tonini G. New molecular targets in bone metastases. *Cancer Treat Rev*. 2010 Nov;36 Suppl 3:S6_S10. Galluzzo S, Vincenzi B, Santini D, Rocci L, Loupakis F, P Corrales, A Raddo, A Zoccoli, A Napolitano, F Graziano, A Ruzzo, S Del Prete, A Falcone, G Francini, G Dicuonzo and G Tonini Early magnesium modifications as a surrogate markers of cetuximab efficacy of cetuximab based anticancer treatment in advanced colorectal cancer patients KRAS wild_type. *Annals of Oncology*, 2010, Nov, 29 B Vincenzi, A Zoccoli, F Pantano, O Venditti, S Galluzzo Cetuximab: FROM BENCH TO BEDSIDE. *Curr Cancer Drug Targets*. 2010 Feb 1;10(1):80_95. Review. Santini D, Fratto ME, Vincenzi B, Napoli N, Caraglia M, Marra M, Abbruzzese A, Caraglia M, Tonini G. Denosumab: the era of targeted therapies in bone metastatic diseases. *Curr Cancer Drug Targets*. 2009 Nov;9(7):834_42. Review. Galluzzo S, Santini D, Vincenzi B, Zoccoli A, Ferraro E, Lippi C., Altomare V., Tonini G., Bertoldo F. Longitudinal evaluation of vitamin D plasma levels during anthracycline and docetaxel based adjuvant chemotherapy in early breast cancer patients. *Ann Oncol*. 2010 Jan;21(1):185_6. S Angeletti, S Galluzzo, D Santini, A Ruzzo, B Vincenzi, E Ferraro, C Spoto, G Lorino, N Graziano, M Magnani, F Graziano, G Tonini and G Dicuonzo. NOD2 polymorphisms impair innate immunity and increase the susceptibility to gastric cancer in Italian population. *Hum Immunol*. 2009 Sep;70(9):729_32. Pantano F, Silletta M, Iovienco A, Vincenzi B, Santini D, Galluzzo S, Bonini S, Tonini G. Stevens Johnson syndrome associated with reduced tear production complicating the use of cetuximab and panitumumab. *Int J Colorectal Dis*. 2009 Feb 19 Vincenzi B, Patti G, Galluzzo S, Pantano F, Venditti O, Santini D, Ruzzo A, Schiavon G, Caraglia M, Marra M, Graziano F, Tonini G. Interleukin 1beta_511T gene (IL1beta) polymorphism is correlated with gastric cancer in the Caucasian population: results from a meta analysis. *Oncol Rep*. 2008 Nov;20(5):1213_20. Santini D, Angeletti S, Ruzzo A, Dicuonzo G, Galluzzo S, Vincenzi B, Calvieri A, Pizzagalli F, Graziano N, Ferraro E, Lorino G, Altomare A, Magnani M, Graziano F, Tonini G Toll like receptor 4 (TLR 4) Asp299Gly and Thr399Ile polymorphisms in gastric cancer of intestinal and diffuse histotype *Clin Exp Immunol*. 2008 Dec;154(3):360_4. Santini D, Fratto ME, Galluzzo S, Vincenzi B, Tonini G. Are bisphosphonates the suitable anticancer drugs for the elderly? *Crit Rev Oncol Hematol*. 2008 Aug 7. Vincenzi B, Santini D, Galluzzo S, Russo A, Fulfaro F, Silletta M, Battistoni F, Rocci L, Zobel BB, Adamo V, Dicuonzo G, Tonini G. Early magnesium reduction in advanced colorectal cancer patients treated with cetuximab plus irinotecan as predictive factor of efficacy and outcome. *Clin Cancer Res*. 2008 Jul 1;14(13):4219_24. Santini D, Martini F, Fratto ME, Galluzzo S, Vincenzi B, Agrati C, Turchi F, Piacentini P, Rocci L, Manavalan JS, Tonini G, Poccia F. In vivo effects of zoledronic acid on peripheral gamma delta T lymphocytes in early breast cancer patients. *Cancer Immunol Immunother*. 2008 May 6 Santini D, Vincenzi B, Galluzzo S, Battistoni F, Rocci L, Venditti O, Schiavon G, Angeletti S, Uzzalli F, Caraglia M, Dicuonzo G and Tonini G. Repeated intermittent low_dose therapy with ZA induces an early, sustained and long_lasting decrease of peripheral vessel endothelial growth factor (VEGF) levels in cancer patients. *Clin Cancer Res*. 2007 Aug 1;13(15 Pt 1):4482_6. S. Galluzzo, D. Santini, B. Vincenzi, N. Caccamo, S. Meraviglia, A. Salerno, F. Dieli and G. Tonini Immunomodulating role of bisphosphonates on human gamma delta T cells-: an intriguing and promising aspect of their antitumor activity. *Expert Opin Ther Targets*. 2007 Jul;11(7):941_54. Review. Santini D., Galluzzo S., Vincenzi B., Schiavon G., Fratto E., Pantano F. and Tonini G. New developments of aminobisphosphonates: the double face of Janus. *Annals of Oncology* 2007, 18 (S6), 164_167. Suciuc Foca N., Feirt N, Zhang Q_Y, Vlad G, Liu Z, Lin H, Chang C_C, Ho E, Colovai A, Kaufman H, D'Agati V, Thaker HM, Remotti H, Galluzzo S, Cinti P, Rabitti C, Allendorf J, Chabot J, Caricato M, Coppola R, Berloco P, Cortesini R. Soluble Ig_like transcript 3 inhibits tumor allograft rejection in humanized SCID mice and T cell responses in cancer patients. *Journal of Immunology*, 2007 Jun 1;178(11):7432_41 Santini D, Fratto ME, Vincenzi B, Galluzzo S, Tonini G. Zoledronic acid in the management of metastatic bone disease. *Expert Opin Biol Ther*. 2006 Dec;6(12):1333_48. Amoroso A., Cacciapaglia F., De Castro S., Battagliese A., Coppolino G., Galluzzo S., Vadacca M., Afeltra A. The adjunctive role of antiphospholipid antibodies in systemic lupus erythematosus cardiac involvement *Clinical and Experimental Rheumatology*, May_Jun 24(3), 287_94. Bruni R., Serino FM, Galluzzo S, Coppolino G, Vadacca M, Nilo S, Termino N, Afeltra A. Alexithymia and Neuroendocrine Immune response in patients with autoimmune diseases: preliminary results on relationship between alexithymic construct and TNF_alpha levels. *Annals of New York Academy of Sciences* 2006 Jun;1069:208_11. Afeltra A, Vadacca M, Conti L, Galluzzo S, Mitterhofer AP, Ferri GM, Del Porto F, Caccavo D, Gandolfo GM, Amoroso A. Thrombosis in systemic lupus erythematosus: congenital and acquired risk factors. *Arthritis Rheum*. 2005 Jun 15;53(3):452_9. Caccavo D, Rigon A, Picardi A, Galluzzo S, Vadacca M, Ferri GM, Amoroso A, Afeltra A. Anti_lactoferrin antibodies in systemic lupus erythematosus: isotypes and clinical correlates. *Clin Rheumatol*. 2005 Aug;24(4):381_7. Epub 2004 Dec 9. Suciuc Foca N, Manavalan JS, Scotto L, Kim_Schulze S, Galluzzo S, Naiyer AJ, Fan J, Vlad G, Cortesini R. Molecular characterization of allospesific T suppressor and tolerogenic dendritic cells: review. *Int Immunopharmacol*. 2005 Jan;5(1):7_11. Review. Scotto L, Naiyer AJ, Galluzzo S, Rossi P, Manavalan JS, Kim_Schulze S, Fang J, Favera RD, Cortesini R, Suciuc Foca N. Overlap between molecular markers expressed by naturally occurring CD4+CD25+ regulatory T cells and antigen specific CD4+CD25+ and CD8+CD28- T suppressor cells. *Hum Immunol*. 2004 Nov;65(11):1297_306. Cortesini NS, Colovai AI, Manavalan JS, Galluzzo S, Naiyer AJ, Liu J, Vlad G, Kim_Schulze S, Scotto L, Fan J, Cortesini R. Role of regulatory and suppressor T_cells in the induction of ILT3+ ILT4+ tolerogenic endothelial cells in organ allografts. *Transpl Immunol*. 2004 Sep_Oct;13(2):73_82. Review. Amoroso A, Gigante A, Gianni C, Amoroso D, Zennaro D, Galluzzo S, Caccavo D. Safety of conventional drugs and biologic agents for Rheumatoid Arthritis. *Eur Rev Med Pharmacol Sci*. 2003 Sep_Oct;7(5):139_45. Review. Caccavo D, Del Porto F, Garzia P, Mitterhofer AP, Galluzzo S, Rigon A, Vadacca M, Navajas MF, Amoroso A, Afeltra A. Raynaud's phenomenon and antiphospholipid antibodies in systemic lupus erythematosus: is there an association? *Ann Rheum Dis*. 2003 Oct;62(10):1003_5. Afeltra A, Garzia P, Mitterhofer AP, Vadacca M, Galluzzo S, Del Porto F, Finamore L, Pascucci S, Gasparini M, Lagana B, Caccavo D, Ferri GM, Amoroso A, Francia A. Neuropsychiatric lupus syndromes: relationship with antiphospholipid antibodies. *Neurology*. 2003 Jul 8;61(1):108_10. Caccavo D, Garzia P, Sebastiani GD, Ferri GM, Galluzzo S, Vadacca M, Rigon A, Afeltra A, Amoroso A. Expression of lactoferrin on neutrophil granulocytes from synovial fluid and peripheral blood of patients with rheumatoid arthritis. *J Rheumatol*. 2003 Feb;30(2):220_4. Amoroso A, Mitterhofer AP, Del Porto F, Garzia P, Ferri GM, Galluzzo S, Vadacca M, Caccavo D, Afeltra A. Antibodies to anionic phospholipids and anti_beta2_GPI: association with thrombosis and thrombocytopenia in systemic lupus erythematosus. *Hum Immunol*. 2003 Feb;64(2):265_73. Amoroso A, Garzia P, Vadacca M, Galluzzo S, Del Porto F, Mitterhofer AP, Afeltra A. The unusual association of three autoimmune diseases in a patient with Noonan syndrome. *J Adolesc Health*. 2003 Jan;32(1):94_7. Afeltra A, Amoroso A, Mitterhofer AP, Vadacca M, Galluzzo S, Francia A, Del Porto F, Gandolfo GM. The 677C > T mutation in the methylenetetrahydrofolate reductase (MTHFR) gene in epileptic patients affected by systemic lupus erythematosus. *Seizure*. 2002 Jun;11(4):250_4. Spoto S, Galluzzo S, De Galasso L, Zobel B, Navajas MF. Prevention of acute tubular necrosis caused by the administration of non_ionic radiologic contrast media. *Clin Ter*. 2000 Sep_Oct;151(5):323_7. Picardi A, Manfrini S, Navajas F, Zardi E, Amicarelli E, De Iorio F, Galluzzo S, Valiani A, Spoto S, Scarlata S, Ves pasiani Gentilucci U, De Galasso L, Meloni MC, Costantino S. 67 year old man with abdominal pain, anorexia and low_grade fever. *Clin Ter*. 2000 Jul_Aug;151(4):287_91. Picardi A, Manfrini S, Navajas F, Amicarelli E, De Iorio F, Valiani A, Galluzzo S, Spoto S, Segna A, Scarlata S, Vespasiani Gentilucci U, De Galasso L, Meloni MC, Costantino S. A 73_year_old woman with vomiting and metabolic alkalosis. *Clin Ter*. 2000 Mar_Apr;151(2):119_23. Amoroso A, Mitterhofer AP, Ferri GM, Galluzzo S, Vadacca M, Afeltra A. Neurological involvement in antiphospholipid antibodies syndrome (APS). *Eur Rev Med Pharmacol Sci*. 1999 Sep_Oct;3(5):205_9. Review.

Projects

Grants _ March 2007 and 2008: grant from Fondazione "Giuliana Cardarelli Mazzi" for research in Translational Oncology. _ April 2009 grant from Italian Minister of University and Research (MIUR). Research activity/projects: _Translational research in oncology; _Immunosurveillance_Immunotherapies; _Angiogenesis and immune system. _Biomarkers predictors of response in different cancers.

Participation and coordination of many clinical trials phase 2b and phase 3 during my work in the Academia setting.

Memberships

Commendation from AIFA General Director (2012). Steering Committee member of ACCELERATE platform (from 2022-to date) Editorial Activity (until 2010) Invited Reviewer of scientific papers for the international Journals "Human Immunology, Elsevier" and Lung Cancer, Elsevier Speaker_discussant "Invited speaker" at National and International meetings in the regulatory field and specifically in paediatrics; on osteoncology and new target therapies in oncology.(until 2010) Presenter of several abstracts at national and International congress (until 2010)

Other Relevant Information

Board Member of University Campus Bio-Medico (January 2022-to date) providing strategic guidance to University research and teaching assets, responsible of financial sustainability of activities.