

## PERSONAL INFORMATION

Sara Galluzzo

## WORK EXPERIENCE

November 2010–Present

**In charge of scientific assessment of medicinal products for immuno-inflammatory diseases, immuno-therapies**

Agenzia Italiana del Farmaco (AIFA), Rome (Italy) (Italy)

At AIFA (Innovation and Pharmaceutical Strategy Division):

- Evaluation of centralized procedures, IT acting as (Co-)Rapporteur at CHMP: product team leader and clinical assessor (efficacy and safety) of medicinal products in the field of immune-inflammatory diseases: immunology/rheumatology, gastrointestinal (IBD); but also immuno-oncology (including biomarkers selection and evaluation);

-Assessment of national scientific advices;

- Evaluation of national dossier for immunological medicinal products in support of CTS and CPR commissions activity;

- Evaluation of clinical trials (phase IIb, III, IV) in support of Clinical Trials Office activity;

-Aifa Observer at the Fase I Commission (National Institute of Health) for evaluation of phase I trials

At EMA:

- Scientific support to IT CHMP members;

- Assessment of EU scientific advices;

- Core member of the Immunology and Rheumatology working group (reviewing or developing guidelines);

-Observer of the Infectious diseases working group (reviewing or developing guidelines);

July 2016–Present

**Italian member at Paediatric Committee (PDCO)**

EMA (European Medicine Agency) (United Kingdom)

Acting as a member of the PDCO (the scientific committee responsible for activities on medicines for children and to support the development of such medicines in the European Union by providing scientific expertise, including assessment of paediatric investigation plans, and defining paediatric needs).

May 2006–November 2010

**Medical Doctor, senior research fellow and lecturer**

Medical Oncology Dept., University Campus Bio-Medico, Rome (Italy) (Italy)

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)

April 2005–May 2006

**Medical Doctor, research fellow**

Clinical Immunology Dept. University Campus Bio-Medico, Rome (Italy) (Italy)

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

## EDUCATION AND TRAINING

- November 2009–November 2010 **M.A. advanced level**  
Catholic University “del Sacro Cuore” of Rome, Italy (Italy)  
Pre-clinical and clinical research and development of drugs: technical, scientific, regulatory and ethical aspects.
- November 2004–November 2007 **PhD**  
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). (United States)  
Experimental Oncology  
Tumor Immunology  
Cellular and molecular biology
- September 2005–September 2006 **M.A.**  
Italian Minister of University and Research (MIUR) (Italy)  
-Approaches of clinical tutoring in the Faculty of Medicine  
-Problem Based Learning model
- July 2003–March 2005 **Post Doctoral Research fellow**  
Columbia University, New York (USA) Dept. of Pathology, Immunology and Immunogenetics laboratory (United States)  
- research activity in immunology and immunogenetics (transplant immunology)  
-cellular and molecular biology techniques
- November 1999–November 2004 **Specialist in Internal Medicine (Clinical Immunology).**  
University “La Sapienza”, Rome (Italy), Fellowship in Internal Medicine (Clinical Immunology oriented). From July 2003 at Columbia University, New York (USA) (Italy)  
- clinical practice (in and out patient)  
- translational research activity in clinical immunology
- November 2001–November 2002 **M.A.**  
Italian Minister of University and Research (MIUR) (Italy)  
Clinical Tutoring:  
-communication, teaching and learning skills  
-problem solving approach applied to students
- September 1993–July 1999 **Medical degree**  
University Campus Bio-Medico, Rome (Italy) (Italy)  
Thesis dissertation: Clinical immunology, autoimmunity  
Graduated magna cum laude.

**ADDITIONAL INFORMATION**

- Expertise**
- 1) Clinical: autoimmunity and autoinflammatory diseases;
  - 2) Experimental oncology, tumor immunology and biology;
  - 3) Pharmaceutical research and drug development, including paediatric medicines ;
  - 4) Regulatory affairs.

## Publications

Co-author of 45 papers on International peer reviewed journals

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, Ersbøll 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- $\kappa$ B (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 Correale, R Addeo, 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 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, Galluzzo S, Tantardini 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, Iovieno 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 gammadelta 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.
- Suciu-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, Terminio N, Afeltra A.  
Alexithymia and Neuroendocrine Immune response in patients with autoimmune diseases: preliminary results on relationship between alexithymic construct and TNF-alfa 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.
- Suciu-Foca N, Manavalan JS, Scotto L, Kim-Schulze S, Galluzzo S, Naiyer AJ, Fan J, Vlad G, Cortesini R.  
Molecular characterization of allospecific 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, Suciu-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, Vespasiani 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.

## Memberships

### Editorial Activity

Invited Reviewer of scientific papers for the international Journals " Human Immunology, Elsevier" and

Lung Cancer, Elsevier

Speaker-discussant (until 2010)

“Invited speaker” at several National and International meetings in the field of osteoncology and new target therapies in oncology.

Presenter of several abstracts at national and International congress.

#### Other Relevant Information