## PERSONAL INFORMATION

Rosa GIULIANI

Sex Female| Date of birth 26 January 1970 | Nationality Italian

## EXPERTISE AT GLANCE

**Breast cancer**: all aspects, with specialist interest in the treatment of metastatic breast cancer, in understanding mechanisms of resistance to treatments, in predicting factors of response, and developing of genomics driven trials.

Extensive training in medical oncology with particular interest for clinical research in the field of breast cancer (Diploma of Specialist in Oncology with Honours awarded by the University La Sapienza in Rome, Diplome d'Etudes Specialisée en Cancerologie_ Diploma of Specialised studies in oncology with honours, awarded by the Free University of Brussels (Université Libre de Bruxelles), and translational research (honorary fellowship at the department of oncology at the Hammersmith Campus, Imperial College, London.

**Clinical research**
PI (local hospital) for several breast cancer trials

**Drug development and Regulatory science (current)**
Clinical Expert for the European Medicines Agency, EMA;
Core member of the Scientific Advisory Group-Oncology (SAG-O), EMA;
Consultant of the committee of expert in oncology for the National Competent Authority (Agenzia Italiana del Farmaco, AIFA).

**Policy in the oncology field**
Chair of the ESMO Global Policy Committee (January 2019)
Member of the ESMO EU Policy Committee;
Member (on behalf of ESMO) of the Healthcare Professional Working Party (HCPWP), EMA; Member (on behalf of ESMO) of the stakeholders group of the Health Technology Assessment Network (HTAN) of the European Commission.

**Organization of international meetings**
Chair of the committee track "Health " of the annual ESMO congress, 2020;
Chair of the committee track "Public health and Economics" of the annual ESMO congress, 2016;
Member of the committee track "Public health and Economics" of the annual ESMO congress, 2017

**Teaching**
ESMO Leaders Generation Programme 2018;
Master of regulatory sciences, University La Sapienza, Rome, IT; academic years 2013/2014 and 2014-2015

## WORK EXPERIENCE

26 November 2018-ongoing (current position)

Locum Consultant Medical Oncologist
Breast cancer group, The Christie NHS Foundation Trust
www.christie.nhs.uk

**Main activities and responsibilities**
-Responsible for overseeing the implementation of delivering bisphosphonates for the treatment of early breast cancer in the Greater Manchester region
-Provision of high quality care to patients with breast cancer, both in adjuvant and metastatic setting at the Christie Hospital, Macclesfield District General Hospital, and Wigan Infirmary.

Business or sector National Health System (NHS)

12 June 2006-23 November 2018

Consultant Medical Oncologist
Medical Oncology Unit and Breast Unit at S. Camillo-Forlanini Hospital, Rome, Italy
www.scamilloforlanini.rm.it

**Main activities and responsibilities**
-Provision of high quality care to patients, mainly with breast cancer, both as outpatients (new diagnosis and treatment, chemotherapy prescriptions, recruitment in clinical trials) and inpatients (ward rounds).
-PI of clinical trials (CDK4/6 inhibitors, immunotherapy, metronomic therapy), active participation to clinical research activities in other trials
-Organization and active participation MDT meetings and internal audits
-Tutoring of junior members of the staff
-Acute oncology
-Participation to the on call rota for night shifts (1:12), for Saturdays (1:7) and for Sundays (1:15)

Business or sector National Health System (NHS)

16 July 2011-15 March 2012

National Expert on secondment (SNE) for the Oncology, Haematology and Diagnostics section of the EMA.

**European Medicines Agency (EMA)**
30 Churchill Place, Canary Wharf, London E14 5EU
www.ema.europa.eu

**Main activities and responsibilities**
Main objective of a clinical SNE is to provide both scientific support and clinical perspective to assist pre- and post-authorization activities of centralized applications/marketing authorizations in line with the European Medicines Agency's mission statement. SNEs should enable the Agency to benefit from the high level of their professional knowledge and experience, in particular in areas where such expertise is not readily available.

Business or sector European Government Agency

December 2008-July 2011

Consultant Medical Oncologist
S. Camillo-Forlanini Hospital, Rome, Italy
www.scamilloforlanini.rm.it

**Main activities and responsibilities**
Same as Work Experience 1 (WE1)

June - November 2008

### Trust Doctor (equivalent SpR) in Medical Oncology

Breast Unit, Dept of Medical Oncology
Charing Cross Hospital
Fulham Palace Road
W6 8RF London, UK

**Main activities and responsibilities**
-Outpatients clinics, ward rounds
-Participation to MDT and other internal meetings (case review with the radiologic team, discussion of difficult cases, et cet.).
-Participation to clinical trials (eg ALTTO trial, SOFEA, et cet.)
-Opportunity to attend the laboratory facilities at Hammersmith Hospital.

Business or sector National Health System (NHS)

12 June 2006-June 2008

### Consultant Medical Oncologist

Medical Oncology Unit, S. Camillo-Forlanini Hospital, Rome, Italy
www.scamilloforlanini.rm.it

**Main activities and responsibilities**
Same as Work Experience 1 (WE1)

September 2005-June 2006

### Honorary Fellowship

MRC Cyclotron building, Cancer medicine, Hammersmith Hospital, London, UK

**Main activities and responsibilities**
Manual phenotyping of circulating cancer cells (CTCs) from breast cancer cell cultures, before the introduction of automated systems, such as Veridex et al.
Training period in order to understand and perform basic technologies such as RT-PCR and immunocytochemistry techniques, which were acquired during the first three months of the fellowship. Then, the objective of the research was to set up a manual system to determine the molecular characteristics of breast cancer cells. It was known at the time that the number of CTCs correlated with PFS and OS in metastatic breast cancer. However, few data were available about the possibility to characterise the molecular profile of CTCs with the aim to tailor treatment.
The experiments formed the rationale to design a clinical study in metastatic setting for patients with breast cancer.

Business or sector Academic, Imperial College, London, UK

January 2004-September 2005

### Attending Physician

Medical Oncology Unit, S. Camillo-Forlanini Hospital, Rome, Italy
www.scamilloforlanini.rm.it

**Main activities and responsibilities**
Same as Work Experience 1 (WE1), but under supervision of the head of the unit.

Outpatient clinics (all cancer types): prescription of chemotherapy, management of side effects, recruitment to clinical trials and global assessment of patient referred to the Unit.
Participation to MDT meeting and audit processes.

Business or sector NHS (Italy)

October 2001-November 2003

### Research Fellow

-Br.E.A.S.T Operational Office, Medical Oncology Department of the Jules Bordet Institute, Brussels (Belgium)
-Breast Unit and ward at the Jules Bordet Hospital

**Main activities and responsibilities**

Clinical and research activities during the fellowship at Jules Bordet Institute were exclusively devoted to breast cancer.
- Medical advisor at the Br.E.A.S.T Operational Office.
Main activity was represented by the strict control of the safety profile of the BIG 02/98-TAX V315 study, by processing the Serious Adverse Events occurred to 2898 patients enrolled in this trial: “An intergroup phase III trial to evaluate the activity of docetaxel, given either sequentially or in combination with doxorubicin, followed by CMF, in comparison to doxorubicin alone or in combination with cyclophosphamide, followed by CMF, in the adjuvant treatment of node-positive breast cancer patients”.
Active participation in other procedures of data analysis for the aforementioned study, e.g. validation of clinical data from a medical standpoint after their collection at the Br.E.A.S.T. operational office was granted.
On demand support to other multicentre international phase III studies coordinated by the Br.E.A.S.T. Operational Office was provided.
- Research fellow at the Translational Research Unit of Jules Bordet Institute.
Tasks in this field included the management of projects specifically addressed to investigate and define predictive factors in the treatment of breast cancer.
Main research was directed to possible mechanisms of resistance to therapies that target the type I growth factor receptor network, e.g. trastuzumab.
The findings of a retrospective study which investigated the phenotype of patients who benefited from trastuzumab versus those who did not, have been presented as posters at several international meetings (ASCO, ECCO, EBCC4) and published in a peer-review journal.

Business or sector Academic, Free University of Brussels and NHS (Belgium)

June 2001-September 2001

### Internship

Br.E.A.S.T Operational Office, Jules Bordet Institute, Brussels (Belgium)

**Main activities and responsibilities**
Understanding of the procedures undertaken by the Breast Office at Jules Bordet Institute as coordinating centre for international clinical trials. Following this internship, a fellowship was started in October 2001

Business or sector Academic, Jules Bordet Institute

December 2000-May 2001

### Attending physician

Sacro Cuore Don Calabria Hospital, Verona, Italy.

**Main activities and responsibilities**
Outpatient clinics (all cancer types): prescription of chemotherapy, management of side effects, and global assessment of patient referred to the Unit.

Business or sector NHS (Italy)

July-September 2001 **Consultant Oncologist for the NGO Ryder Italia**

**Main activities and responsibilities**
Delivery of best supportive care to patients with metastatic cancers in advanced phase. Palliative treatment was given at patients' home.

Business or sector NGO, Italy

## EDUCATION AND TRAINING

October 2001-September 2003 **Diplôme d'Etudes Specialisée en Cancerologie with Distinction (Fellowship in Medical Oncology) awarded by the Free University of Brussels**

Discussed thesis: Molecular markers predicting the efficacy of single-agent trastuzumab in patients with HER2-overexpressing metastatic breast cancer.

Skills acquired:
Undestanding the procedures needed to run both translational and high level clinical research.
Improved ability in the treatment of patient with early and metastatic breast cancer

October 1996-December 2000 **Specialist degree in Medical Oncology awarded by the University of Rome "La Sapienza", with mark of 70/70 with Honors.**

May-October 1999 **Observership at MD Anderson Cancer Center, Houston, Texas, US.**
The observership period was split between the Breast Dept (Head, Dr G. Hortobagyi) and the Thoracic/Head&Neck Dept (Head W.K. Hong).

November 1989-April 1996 **Medical Degree awarded by the University of Rome, "La Sapienza", with mark of 110/110 with Honors.**

## PERSONAL SKILLS

Mother tongue Italian

Other language(s)

| | UNDERSTANDING | | SPEAKING | | WRITING |
|---|---|---|---|---|---|
| | Listening | Reading | Spoken interaction | Spoken production | |
| English | C1 | C1 | C1 | C1 | C1 |
| | IELTS certificate (4 March 2017) | | | | |
| French | B2 | B2 | B2 | B1 | A2 |
| | Self-assessment | | | | |

German A1, beginner

Communication skills

Good communication skills gained while studying and working in several EU countries (Italy, Belgium and United Kingdom) and in different settings (hospital, laboratory, regulatory agency). These experiences allowed me to enjoy the interaction with patients of different cultural background and forged my ability to adapt to different environments.

Technical skills

Good command of Microsoft Office and of search systems/engines.

Organisational / managerial skills

-Ability to coordinate working groups and research groups.
-Natural inclination to networking and collaboration with people from different cultural and working environments.
- Sense of pragmatism and genuine attitude to have thing done.

As examples:

-Chair of the track "Public health and health economics" of the 41th annual Congress of the European Society for Medical Oncology (ESMO), 2016.

-Member of the track "Public health and health economics" of the 42th annual of the European Society for Medical Oncology (ESMO), 2017.

-Co-Director of the course "Advanced course on Breast Cancer Management", S. Camillo-Forlanini Hospital, 25 September 2010.
The course was attended by >100 participants, mainly from Spain and Italy, with experts in clinical and translational research in breast cancer.

-Scientific responsible and teacher at the CME course "Audit in Medical Oncology" at the Medical Oncology unit of S. Camillo-Forlanini Hospital, edition 2009-2010.

-Lecturer in the Master of regulatory sciences of Medicines academic years 2013/2014 and 2014-2015
Department of Physiology and Pharmacology of the University of Rome, "La Sapienza".

-Scientific director of the CME course "Updates on breast cancer", 1st edition, June-December 2016, Breast Unit, S. Camillo-Forlanini Hospital.

-Lecturer at the ESMO Leaders Generation Programme 2018 organized by ESMO.

-Co-chair of the topic group academia that worked to update the document "Framework for interaction with Academia" in the context of the HCPWP of EMA.

CLINICAL RESEARCH

-**Principal Investigator (for the local hospital)** of the clinical trials "A Randomized, Double-Blind, Phase III Study of Pembrolizumab (MK-3475) plus Chemotherapy vs Placebo plus Chemotherapy for Previously Untreated Locally Recurrent/inoperable or Metastatic Triple Negative Breast Cancer – (KEYNOTE- 355)".

- **Principal Investigator (for the local hospital)** of the clinical trial "An open-label, multicenter, Phase IIIb study to assess the safety and efficacy of ribociclib (LEE011) in combination with letrozole for the treatment of men and pre/postmenopausal women with hormone receptor-positive (HR+), HER2-negative (HER2–) advanced breast cancer (ABC) with no prior hormonal therapy for advanced disease".

- **Principal Investigator (for the local hospital)** of the study "METEORA trial (MEtronomic TrEatment Option in advanced bReast cAncer), which is a collaborative trial with the IBCSG (International Breast Cancer Study Group)". Submitted to the EC.

-**Sub-investigatore** of the study "A phase II randomized, double-blind, placebo-controlled trial of radium-223 dichloride in combination with exemestane and everolimus versus placebo in combination with exemestane and everolimus when administered to metastatic HER2 negative hormone receptor positive breast cancer subjects with bone metastases.

MEMBERSHIPS

-Member of the "European Society for Medical Oncology" (ESMO)
- Member of Flims Alumni Club (FAC). From 2003-2006 FAC Steering Committee member
- 2004-2007 Associate Member of American Association for Cancer Research (AACR)

GRANTS

-AMERICAN ITALIAN CANCER FOUNDATION Fellowship for the year 2005-2006

-EUROPEAN ORGANIZATION for RESEARCH and TREATMENT of CANCER (EORTC) grant for Young Oncologists (2005)

Driving licence

B

Registration with Medical Orders

-Licence to practice n° M47781 released by the Provincial Order of Physicians, Surgeon and Dentists of Rome in 1996

-Registered in the specialist register of the General medical council since 28 December 2017 (reference number 7019883)

High Level Skills and Competences

**-Core member of the Inter-Committee SCIENTIFIC ADVISORY GROUP on ONCOLOGY (SAG-O) of the European Medicines Agency (EMA) from March 2012.**
The SAG-O is constituted by independent European experts with acknowledged experience in the oncology and haematology field.

The Committee is convened at the request of any of the EMA committees, particularly and more frequently of the CHMP (Committee for Medicinal Products for Human use) in order to discuss and clarify specific issues emerged in the advanced phase of assessment of new drugs for which the marketing authorization is required. Also, the SAG-O may be requested to provide recommendation on any other work of the Agency, such us clinical guidelines, biomarkers development, et cet.

- **Member of the EU Policy Committee of the European Society for Medical Oncology (ESMO).**
The EU Policy Committee addresses political topics of concern to ESMO and its members, with a specific focus on promoting the practice and the profession of medical oncology and diminishing the discrepancies in the quality of cancer care. In particular, access to innovative drugs in EU is a topic of interest for me within the committee.

**-Chair of the ESMO Global Policy Committee (since January 2019)**

**-Representative on behalf of ESMO in the Healthcare-Providers group of the HTA Network coordinated by the European Commission.**

The HTAN was constituted by the European Commission with the aim to facilitate the cooperation between EU Member States in the health technology assessment of innovative drugs and technologies. A pool of stakeholders (healthcare professionals, patient and consumers, industry, payers) was selected following the launch of a call. This pool follows the work of the HTAN in the capacity of observer. However, the members are requested to provide input on specific topics. ESMO is among the selected stakeholders.

**-Representative on behalf of ESMO in the "Healthcare Professionals Working Party" (HCPWP) of EMA.**

HCPWP is composed by representatives of eligible European healthcare organizations. HCPWP "supports the Agency in accessing the best independent expertise in any matter related to medicines; contribute to more efficient and targeted communication to healthcare professionals; enhance understanding of the role of the EU medicines regulatory network".
A topic group "academia" was constituted with the temporary mandate to update the document "Framework for interaction with Academia" that covers the objectives of the collaboration between the academia and EMA. I acted as co-chair of the academia topic group.

**-Member (up to 2016) of the stakeholders forum for EUnetHTA (European Network of HTAs).**

EUnetHTA is a voluntary network of government organizations, which collaborates to define procedures and technical tools agreed by and shared with EU Member States with the aim to facilitate the collaboration in the HTA field in EU. EUnetHTA was constituted in 2010 and worked through sequential Joint Actions (JA). The third JA (2016-2020) is currently ongoing with the objective to promote the implementation at European level of the set of methodological tools develop so far (e.g Relative Efficacy Assessment, REA).

Up to 2016 EUnetHTA had a pool of stakeholders including representative of academic societies, patients' advocates, industry and payers. Main task of the pool was to provide input on specific methodologies and procedures developed by EUnetHTA administrators. ESMO was among the eligible organizations of stakeholders pool.

**-Member of the advisory committee for the Italian Agency for Medicines (AIFA).**
The committee is composed of national experts in the field of haematology and oncology and has the task to provide opinions at the request of the Technical-Scientific Commission (CTS) of AIFA.

**- External clinical assessor for AIFA (up to 2015).**
The external clinical assessor belongs to the team of Rapporteur or Co-Rapporteur that evaluate the data submitted by Pharmaceutical Companies to EMA in the context of the dossier which is meant to support the request of the marketing authorization. In this capacity, I have mainly focused on the efficacy section of several innovative drugs. The document finalised by the two teams of the Rapp and Co-Rapp will be then discussed tat the monthly CMHP meeting for final approval and will hesitate in the European Public Assessment Report (EPAR) which will be published in the EMA website.

- **External clinical expert in the evaluation of the design of clinical trials,** which are submitted to AIFA for approval to be conducted on national territory. The Office of research and clinical development (AIFA) is the competent authority for clinical research and has the task to grant the permission to run the submitted studies. The Office may request the expertise of external clinical experts that provide their opinion on appropriateness of the study design.

## Publications

1. Cortesi E., Giuliani R. et. al. Rapporti tra oncologo ed analgesista. Atti del IV Corso di Aggiornamento Terapia Antalgica nel Dolore Oncologico. Roma 11/4/98 (Italian Language)

2. Cortesi E., Giuliani R., et al.: Le terapie eroiche tra quantità e qualità di vita. Quaderni di Cure Palliative n°4/1996 (Italian Language)

3. Moscetti L, Saltarelli S, Giuliani R et al. Intra-arterial liver chemotherapy and hormone therapy in malignant insulinoma: case report and review of the literature. Tumori 2000; 86(6) 475-479

4. Cortesi E., Giuliani R, Accettura C. Regional chemotherapy: where is the place for it? Dig Surg 2000; 17: 95-96

5. Cortesi E., Giuliani R, Mancuso A., Paoluzzi L. Colon cancer: is adjuvant therapy whorthwile? Dig Sur 2000; 17:100-101

6. Sobrero A, Zaniboni A, Giuliani R, et al. Schedule specific biochemical modulation of 5-fluorouracil in advanced colorectal cancer: a randomized study. Ann Oncol 2000; 11: 1413-1420

7. Di Leo A., Cardoso F., Durbecq V., Giuliani R, et al. Predictive molecular markers in the adjuvant therapy of breast cancer: state of the art in the year 2002. Int J Clin Oncol, 2002. 7: 245-253

8. Mancuso A, Giuliani R, Accettura C, et al. Hepatic arterial continuous infusion (HACI) of oxaliplatin in patients with unresectable liver metastases from colorectal cancer. Anticancer Res 2003 Mar-Apr; 23 (2C): 1917-22

9. Awada A, Cardoso F, Atalay G, Giuliani R, et al. The pipeline of new anticancer agents for breast cancer treatment in 2003. Critical Reviews in Oncol/Hematology, October 2003; 48: 45-63

10. The Epirubicin Monitoring Plan Investigators. Risk of acute myeloid leukemia and Myelodysplastic syndrome in trials of adjuvant epirubicin for early breast cancer: correlation with doses of epirubicin and cyclophosphamide. J Clin Onc 2005; 23: 4179-91.

11. Giuliani R, Durbecq V, Di Leo A, et al. Phosphorylated HER-2 tyrosine kinase and Her-2/neu gene amplification as predictive factors of response to trastuzumab in patients with HER-2 overexpressing metastatic breast cancer (MBC). Eur J Cancer 2007 Mar; 43(4): 725-35.

12. Francis P, Crown J, Di leo A, et al BIG 02-98 collaborative group. Adjuvant chemotherapy with sequential or concurrent anthracycline and docetaxel: Breast International Group 02-98 randomized trial. J Natl Cancer Inst 2008 Jan; 100(2): 121-33. R. Giuliani is quoted in the Notes section, within the Breast Office Jules Bordet Brussels team that contributed to the study.

13. Desmedt C, Sperinde J, Piette F, Giuliani R, et al. Quantitation of HER2 expression orHER2: HER2 dimers and differential survival in a cohort of metastatic breast cancer patients carefully selected for trastuzumab treatment primarily by FISH. Diagn Mol Pathol. 2009 Mar; 18(1): 22-9

14. Tuthill M, Pell R, Giuliani R et al. Peritoneal disease in breast cancer: a specific entity with an extremely poor prognosis. Eur J Cancer 2009, 45 (12): 2146-2149

15. De Azambuja E, McCaskill-Stevens W, Francis P, Quinaux E, Crown JP, Vicente M, Giuliani R, et al. The effect of body mass index on overall and disease-free survival in node-positive breast cancer patients treated with docetaxel and doxorubicin-containing adjuvant chemotherapy: the experience of the BIG 02-98 trial. Breast Cancer Res Treat. 2010 Jan; 119 (1): 145-53.

16. Giuliani R, Sternberg C: "The NEJM publication of a phase II trial accompanied by an editorial reflects the exceptional..." Evaluation of: [O'Shaughnessy J et al. Iniparib plus chemotherapy in metastatic triple-negative breast cancer. N Engl J Med. 2011 Jan 20; 364(3): 205-14; doi:10.1056/NEJMoa1011418]. Faculty of 1000, 10 Feb 2011. F1000.com/8186975

17. Giuliani R, Sternberg C: "The article "The hallmarks of cancer", published in 2000, is the most cited..." Evaluation of: [Hanahan D, Weinberg RA. Hallmarks of cancer: the next generation. Cell. 2011 Mar 4; 144(5):646-74; doi: 10.1016/j.cell.2011.02.013]. Faculty of 1000, 27 Jul 2011. F1000.com/12135956

18. Sternberg CN and Giuliani R. Evaluation of: [Vogelzang NJ et al. Clinical Cancer Advances 2011: Annual report on progress against cancer from the American Society of Clinical Oncology]. Faculty of F1000, 29 Feb 2012. F1000.com/13931975.

19. Pean E, Klaar S, Giuliani R et al. The European Medicines Agency review of eribulin (Halaven) for the treatment of patients with locally advanced or metastatic breast cancer: summary of the scientific assessment of the Committee for Medicinal Products for Human Use (CHMP). Clin Cancer Res 2012; 18: 4491-7.

20. Paola ED, Alonso S, Giuliani R et al. An open-label, dose finding study of the combination of satraplatin and gemcitabine in patients with advanced solid tumors. Front Oncol 2012; 22: 2:175

21. Da Rocha Dias S, Salmonson T, Giuliani R et al. The European Medicines Agency review of vemurafenib (Zelboraf) for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma: summary of the scientific assessment of the Committee from Medicinal Products for Human Use (CHMP). Eur J Cancer 2013; 49: 1654-1661.

22. Gravanis I, Lopez AS, Hemmings RJ, Giuliani R et al. The European medicines agency review of abiraterone for the treatment of metastatic castration-resistant prostate cancer in adult men after docetaxel chemotherapy and in chemotherapy naive disease: summary of the scientific assessment of the committee for medicinal products for human use. Oncologist 2013; 18: 1032-42.

23. Natoli et al. Breast cancer "tailored follow-up" in Italian oncology units: a web-based survey. PLoSOne 2014 April 8; 9 (4): e94063.

24. Boix-Perales H, Borregaard J, Jensen KB, Ersboll J, Galluzzo S, Giuliani R, et al. 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; 19: 766-73.

25. Moscetti L, Vici P, Gamucci T, Natoli C, Cortesi E, Marchetti P, Santini D, Giuliani R, et al. Safety analysis, association with response and previous treatments of everolimus and exemestane in 181 metastatic breast cancer patients: A multicenter Italian experience. Breast. 2016 Oct; 29:96-101.

26. Tabernero J, Vyas M, Giuliani R, et al. Biosimilars:a position paper of the European Society for Medical Oncology, with particular reference to oncology prescribers. ESMO Open. 2017 Jan 16;1(6):e000142. doi: 10.1136/esmoopen-2016-000142. eCollection 2016. Review

27.Giuliani R. Are Biosimilars-Bio the Same? The clinical Perspective. ESMO Perspective. E-jornal; Issue 3, March 2017. http://magazine.esmo.org/perspectives-3/#!/feature-biosimilars

28. Wolff-Holz E, Garcia Burgos J, Giuliani R, et al. Preparing for the incoming wave of biosimilars in oncology. ESMO Open. 2018 Sep 5;3(6):e000420. doi: 10.1136/esmoopen-2018-000420. eCollection 2018.

29. Giuliani R, Tabernero J, Cardoso F. et al. Knowledge and use of biosimilars in oncology: a survey by the European Society for Medical Oncology (ESMO). *ESMO Open* 2019;**4:**e000460. doi: 10.1136/esmoopen-2018-000460

CITATIONS 820
H-INDEX 15

(source: Google scholar)

https://scholar.google.com/citations?hl=it&view_op=list_works&gmla=AJsN-F7s5GGsa4C4gHyuL2vmPE_HZEpLX8rN_yBL9P96U1-EqKLzAQcuZVluitP0OFr8kYriSMu9ZP17phJfazqf0HFp3tCdLPcQsRVyPelUkXPL11s_iHTMSgg4ogelYRfy0mnBUWyM&user=JosPG3wAAAAJ

## Presentations at Conferences

1. Presentazione orale in sessione plenaria al XVI meeting nazionale di oncologia medica "A randomized trial in advanced colorectal cancer (ACRC): sequential MTX->FU vs schedule specific biochemical modulation". Rome, November 15-18, 1998.

2. Investigator perspective in the conduction of clinical trials. Pre-investigator oncology training session for CCI studies (Wyeth Lederle). April 17, 2002, Dolce, Chantilly, France.

3. "Post-ASCO 2005: updates about endocrine-therapy for breast cancer". June 24-25, 2005, Gubbio, Italy.

4. Trastuzumab in breast cancer. Scarperia, Florence, Italy, 16 June 2007

5. HPV vaccine: a gift for women's health. Cervical cancer: epidemiology in Italy. Italian Red Cross meeting, Rome 12 May 07

6. Grand round meeting. Not all drugs are created equal. Hammersmith Hospital, 16 July 2008, London, Uk

7. ToGetErb. The new therapeutic option for HER2 positive breast cancer. Istituto Regina Elena, Rome, Italy 11 May 2009.

8. Breast cancer meeting: overview on new drugs. S. Camillo-Forlanini Hospital, 25 November 2009, Rome, Italy

9. Molecular markers and new treatments for breast cancer. S. Giovanni-Addolorata Hospital, 5 March 2010, Rome, Italy

10. Overcoming mechanisms of resistance to HER2 therapies. Advanced course on breast cancer management, S. Camillo-Forlanini Hospital, 25 September 2010

11. Anti-HER2 therapies for advanced breast cancer: when drugs development met biological rational. Lecture at the 3rd course for Molecular biology applied to clinical practice, 24-25 June 2011, Rome

12. Anti-HER2 therapies for advanced breast cancer. 12 and 26 September 2011, EMA, London

13. Cardiotoxicity beyond anthracyclines. Lecture at the European Society of Cardiology (ESC) meeting. Munich 28 August 2012

14. Erythropoiesis stimulating agents (ESA): problems of distribution, interaction and efficacy in the era of targeted therapies. 4th course for Molecular Biology applied to clinical practice, 9-10 May 2013, Rome

15. Cancer drugs: main hurdles in the assessment of the regulatory files. Oncology advisory groups of the EMA groups. Master in regulatory science. University "La Sapienza". 24 May, 2013 and 11 April 2014, Rome.

16. Narrowing the gap between regulatory and HTA demands. "Spring Pharm Access Leaders" Forum event, Paris 19-21 May 2014.

17. Regulatory dilemma in immunotherapy of cancer. CDDF 8th Alpine Conference. Buchen/Innsbruck, 2-4 March 2015.

18. Generics and biosimilars: perception by the medical community, evaluation, proof of efficacy, approval, quality control. Joint session RUSSCO-ESMO Federation, at annual RUSSCO meeting. Moscow, 17 November 2015.

19. Il trattamento del tumore della mammella nell'era della medicina di precisione: siamo poi così precisi ? Impatto delle terapie a bersaglio molecolare in Oncologia. San Camillo Conferences 2015. Roma, 17 Dicembre 2015.

20. Medical communications: how would doctors like to receive scientific data? VI edition Medical affairs, Leaders forum Europe. Berlin, 22-23 February 2016.

21. The regulatory process for approval of drugs based on biomarkers. V AIOM-ESP-ESMO-SIAPEC meeting. Naples, 8-9 April 2016.

22. Neo-and adjuvant treatment of HER2 positive breast cancer. University La Cattolica, Rome, 22 April 2016.

23. Product value in the eyes of physicians: how would doctors like to receive scientific data. PharmAccess Leaders" Forum, Berlin 27-29 September 2016.

24. The EMA approach: what level of diagnostic confidence or certification is needed for early stage clinical trials

and adaptive applications. **28th EORTC-NCI-AACR symposium on 'Molecular targets and cancer therapeutics'.** Munich 29 November- 2 December 2016.

25. Adaptive pathways: perspectives of patients and healthcare professionals on addressing patient needs. Adaptive pathways workshop, European Medicines Agency, London, 8 December 2016.

26. Regulatory perspectives on clinical outcomes and role of surrogate markers. Pan tumor scientific exchange meeting. Rome 9-10 February 2017.

27. **Biomarkers**-Lost in translation. A regulatory perspective. Current and Future Challenges for Innovative Biomarker Development. Meeting organised by the CM-Path and the Institute of Cancer Research. **Royal Society of Medicine, London, 12 April 2017**

28. ESMO EU Policy Committee initiatives for improved access to innovative medicines. 13th Annual Congress of the European Association of Dermato- Oncology. Athens, 3-6 May 2017

29. A clinical/regulatory perspective on experience with biomarkers in EU approvals. Outlook and challenges. Innovation in oncology clinical trial design. Cancer Drug Development Forum (CDDF), Frankfurt, 12-13 June 2017

30. Clinician's perspective: building confidence to prescribe biosimilars. ESMO position paper on biosimilars. Special session: the incoming wave of biosimilars in Oncology. ESMO Annual Congress, Madrid 8-12 September 2017.

31. Challenges in regulation. Special Symposium: access to innovative drugs in the EU. ESMO Annual Congress, Madrid 8-12 September 2017.

32. Discussant of abstracts 1400-41-42 at the Poster Discussion session-Public Health Policy and Health Economics. ESMO Annual Congress, Madrid 8-12 September 2017.

33. Adaptive pathways and innovative medicines development for improved access. Panel discussion. Value, Access and regulatory strategy workshop.25-26 October, Basel, Switzerland.

34. Evolution of product development to respond to the future needs. Panel discussion. Value, Access and regulatory strategy workshop.25-26 October, Basel, Switzerland.

35. Workshop on Site and Histology –Independent Indications in Oncology. Chair of Panel Discussion 5. EMA, London 14-15 December 2017

36. How can doctors be better engaged in evidence generation. Medaffairs Leaders" Forum, London 27 Feb-1 March 2018.

37. Clinician's perspective in prescribing biosimilars. Synergy Satellite Session: Biosimilars in cancer care - the next challenge**.** 23rd Congress of the European Association of Hospital Pharmacists (EAHP) 21- 23 March 2018, Gothenburg, Sweden.

38. Relationship between oncologist and nurse: professionalisms in the managements of the oncology units. Rome, 26 March 2018.

39. The European Medicines Agency. How is it structured? How does it work? How are decisions made? ESMO Leaders Generation Programme 2018. Lugano, 22 Apil 2018.

40. Understanding issues and challenges_Biosimilars debate: a clinician's view. EuropaColon 3rd advocacy masterclass. 20th ESMO World Congress on Gastrointestinal Cancer. 22 June 2018.

41. The role of physicians in prescribing biosimilars and creating opportunities for sustainable cancer care . European Commission Stakeholder Event on Biosimilar Medicinal Products Brussels, 14 September 2018.

42. Biosimilars – what they are and their use in oncology. ESMO 2018, Young Oncologists brunch session, Munich, 22 October 2018.

43. Biosimilars in solid tumors_ ESO conference "Biosimilars in Cancer Care: Challenges and opportunities for Health Professionals and Patients", Barcelona, 17 November 2018.