EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

PERSONAL INFORMATION

Rosa Giuliani

WORK EXPERIENCE

September 2019- Present

Consultant in Medical Oncology

The Clatterbridge Cancer Centre (United Kingdom)

Provision of care to patient with breast cancer

Acute Oncology

Clinical trials participation and development

November 2018-August 2019

Locum Consultant in medical oncology

The Christie NHS Foundation Trust (United Kingdom)

-Consultant for the Adjuvant bisphosphonate service, which was set up to offer bisphosphonates to all eligible patients with early breast cancer.

-The job requires also to provide clinical activities in the breast oncology unit at Macclesfield and Wigan hospitals.

June 2006- Present

Consultant in Medical Oncology, permanent position

S. Camillo-Forlanini Hospital, Rome. National Health System (Italy)

Full time permanent job that requires the management of patients with solid tumors, both as in- and out patients. Participation to multidisciplinary meetings and to internal meetings (journal club morbidity/mortality meetings and research meetings) is requested on regular basis (once a week for each meeting). Clinical trials, phase I-II-III trials are run in the centre and the enrollment of patients in trials is strongly recommended.

I have independent responsibility in performing and supervising the audit projects regarding breast cancers, as well as coordinating the presentations at the 1) multidisciplinary meetings, 2) journal club meeting

July 2011-March 2012

National Expert on secondment (SNE)

H-SE-ONC - Oncology, Haematology and Diagnostics section of the Human safety and Efficacy Sector, European Medicines Agency (EMA) (United Kingdom)

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 Agencys 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.

December 2008-July 2011

Consultant in Medical Oncology

S. Camillo-Forlanini Hospital, Rome, National Health System (Italy)

please, refer to WE 1

June 2008-November 2008

Trust Doctor (SpR) in Medical Oncology

Directorate of Cancer Services, Charing Cross Hospital (Medical Oncology specializing in Breast Cancer), London, UK. (United Kingdom)

Management of patients, both in- and outpatients with breast cancer.

Participation to research activities, including laboratory research at Hammersmith Hospital and multidisciplinary meetings

June 2006-May 2008

Consultant in Medical Oncology

S. Camillo-Forlanini Hospital, Rome (National Health System) (Italy)

Please refer to WE 1 and 3

September 2005-June 2006

Honorary fellowship

Cancer medicine, Hammersmith Hospital, London (United Kingdom)

The fellowship was devoted to the development of new tools to phenotype circulating cancer cells (CTCs), from breast cancer cell cultures. The experiments required basic knowledge of RT-PCR and immunocytology 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 pull out and study breast cancer cells, from cultures and from blood. The number of CTCs was shown to correlate with PFS and OS in metastatic breast cancer. The experiments aimed to demonstrate that phenotyping breast cancer cells is as feasible as counting them. That will possibly allow tailoring the specific biologic therapy for breast cancer patients. The experiments formed the rationale to design a clinical study in metastatic setting for patients with breast cancer.

January 2004-September 2005

Attending physician (temporary position)

Medical Oncology Unit of S. Camillo-Forlanini Hospital. Chief of Medical Oncology (Italy)

In charge of health care for both in- and outpatients with solid tumors.

Tasks encompassed prescription of chemotherapy regimens, management of chemotherapy toxicity and global assessment of patient referred to the Unit, including their enrollment in clinical trials.

October 2001-November 2003

Research fellow

Br.E.A.S.T Operational Office, Medical Oncology Department of the Jules Bordet Institute, Brussels (Belgium)

Clinical and research activities during the fellowship at Jules Bordet Institute were exclusively devoted to breast cancer.

- Medical adviser 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.

Occasional support to other multicenter 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 (European Journal of Cancer).

July 2001-September 2001

Consultant Oncologist

Ryder Italia, No profit association for home-based supportive cancer care (Italy)

Global clinical assessment for the delivery of the best supportive care to patients with advanced disease. Care was delivered at patients home

EDUCATION AND TRAINING

November 1989-April 1996

Medical degree with Honors

University of Rome, La Sapienza (Italy)

1996- 1996

Qualifying examination (licence to practice) and registration with the Medical Council

Medical Council of Rome (Italy)

Licence to practice

October 1996-December 2000

Medical Oncology specialty degree with Honors

University of Rome, La Sapienza (Italy)

Medical Oncology, Specialty training. The training was accomplished according to the European Community Directives for Medical Oncology.

The medical oncology specialty has been recognized on EU level (Directive 2005/36/EC)

May 1999-October 1999

Observership

Observership at the Breast Dept (Head, Dr G. Hortobagyi) and at the Thoracic/Head&Neck Dept (Head W.K. Hong) (United States)

June 2001-June 2001

Obervership

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

Understanding procedures undertaken by the Breast Office at Jules Bordet Instiute. After the observership in June, a fellowship was offered (please refer to WE 8 and ET 6

October 2001-September 2003

Diplôme dEtudes Specialisée en Cancerologie with Distinction (Fellowship in Medical Oncology)

Université Libre de Bruxelles (Belgium)

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

ADDITIONAL INFORMATION

Expertise

Medical Oncology
Breast cancer
Clinical drugs development
Regulatory drugs approval
Cancer Policy

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. 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
5. 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
6. 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
7. 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
8. 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.
9. 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.
10. 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.
11. Desmedt C, Sperinde J, Piette F, Giuliani R, et al. Quantitation of HER2 expression or HER2: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
12. 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
13. 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.
14. 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
15. 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
16. 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.
17. 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.
18. 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
19. 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 fro Medicinal Products for Human Use (CHMP). Eur J Cancer 2013; 49: 1654-1661.
20. Gravanis I, Lopez AS, Hemmings RJ, Giulianir 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.
21. Natoli et al. Breast cancer "tailored follow-up" in Italian oncology units: a web-based survey. PLoS One 2014 April 8; 9 (4): e94063.
22. 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.
23. 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.
24. Tabernero J, Vyas M,Giuliani R, et al. Biosimilars:a position paper of the European Society for MedicalOncology, with particular reference to oncology
prescribers. ESMO Open. 2017 Jan 16;1(6):e000142. doi: 10.1136/esmoopen-2016-000142. eCollection 2016. Review

Projects

-Director of the ESMO Public Policy (Jan 2020-ongoing)
-Chair of Public Policy track of the ESMO annula Congress 2020
-Chair of the Public health and health economics sub-committee track of the 41st European Society for Medical Oncology (ESMO), 2016
-Member of the Public health and health economics sub-committee track of the 42nd European Society for Medical Oncology (ESMO), 2017
-From March 2012 Core member of the Scientific Advisory Group-Oncology for the European Medicines Agency
-From August 2013 February 2016 member of the stakeholder forum of EUnetHTA
-From March 2014 till 2015 External clinical assessor for the Italian Medicines Agency (AIFA)
-From 2012 Member of the ESMO EU policy committee
-From October 2013 ESMO representative in the healthcare providers of the EU HTA Network
-ESMO representative in the Healthcare professionals working party (HCPWP) of the EMA
-In 2011 Associate faculty member of the F1000 website (www.f1000.com).
GRANTS
- American Italian Cancer Foundation Fellowship for the year 2005-2006
- EORTC grant for Young Oncologists (2005)
MANAGERIAL SKILLS
-Co-director of the course Advanced course on Breast Cancer Mangement at S.Camillo-Forlanini Hosptal, 25 September 2010.
- Lecturer and co-manager of the programme Audit in Medical Oncology at S. Camillo-Forlanini Hospital, 2009-2010
- Director of the CME accredited course "Update on breast cancer", May-December 2016, Breast Unit, S. Camillo-Forlanini hospital, Rome.
-Chair of the committee drafting guidelines on the prescription and risk managementof bisphosphonates for cancer patients at S. Camillo-Forlanini hospital, 2017.
CLINICAL TRIALS
PI (local hospital) for the clinical study "A Randomized, Double-Blind, Phase III Study of Pembrolizumab (MK-3475) plus Chemotherapy vs Placebo plus Chemotherapy for Previously Untreated Locally RecurrentInoperable or Metastatic Triple Negative Breast Cancer (KEYNOTE-355)". Study active, recruiting_January 2018.
PI (local hospital) for the clinica study 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. Study active, accrual completed December 2017.
PI (local hospital) for the clinical 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 EC.
Sub-investigator for the clinical 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. Active closed to accrual at

January 2018.

Memberships

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

Other Relevant Information

LANGUAGES:
1) English: reading, writing and verbal skills: good command (C2)
2) French: good command, reading C1, writing A2, verbal skills B2
3) German: Beginner A1
LECTURES
- Oral presentation at the XVI National Italian Meeting of Clinical and Experimental Oncology, Plenary Session. Rome, November 15-18, 1998.
A randomized trial in advanced colorectal cancer (ACRC): sequential MTX->FU vs schedule specific biochemical modulation
-Investigator perspective in the conduction of clinical trials. Pre-investigator oncology training session for CCI studies (Wyeth Lederle). April 17, 2002, Dolce, Chantilly, France.
- Post-ASCO 2005: updates about endocrine-therapy for breast cancer. June 24-25, 2005, Gubbio, Italy.
- Trastuzumab in breast cancer. Scarperia, Florence, Italy, 16 June 2007
- HPV vaccine: a gift for womens health. Cervical cancer: epidemiology in Italy. Italian Red Cross meeting, Rome 12 May 07
- Grand round meeting. Not all drugs are created equal. Hammersmith Hospital, 16 July 2008, London, Uk
- ToGetErb. The new therapeutic option for HER2 positive breast cancer. Istituto Regina Elena, Rome, Italy 11 May 2009.
- Breast cancer meeting: overview on new drugs. S. Camillo-Forlanini Hospital, 25 November 2009, Rome, Italy
- Molecular markers and new treatments for breast cancer. S. Giovanni-Addolorata Hospital, 5 March 2010, Rome, Italy
- Overcoming mechanisms of resistance to HER2 therapies. Advanced course on breast cancer management, S. Camillo-Forlanini Hospital, 25 September 2010
- 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
- Anti-HER2 therapies for advanced breast cancer. 12 and 26 September 2011, EMA, London
- Cardiotoxicity beyond anthracycline. Lecture at the European Society of Cardiology (ESC) meeting. Munich 28 August 2012
- Erythropoiesis stimulating agents (ESA): problematics 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
- 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.
- Narrowing the gap between regulatory and HTA demands. "Spring Pharm Access Leaders" Forum event, Paris 19-21 May 2014.
- 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.
- Regulatory dilemma in ummunotherapy of cancer. CDDF 8th Alpine Conference. Buchen/Innsbruck, 2-4 March 2015.
- Medical communications: how would doctors like to receive scientific data? VI edition Medical affairs, Leaders forum Europe. Berlin, 22-23 February 2016.

- The regulatory process for approval of drugs based on biomarkers. V AIOM-ESP-ESMO-SIAPEC meeting. Neaples, 8-9 April 2016.
-Neo-and adjuvant treatment of HER2 positive breast cancer. University La Cattolica, Rome, 22 April 2016.
-Product value in the eyes of physicians: how would doctors like to receive scientific data. PharmAccess Leaders" Forum, Berlin 27-29 September 2016.

- 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 therapeutcis'. Munich 29 november- 2 December 2016.
- Adaptive pathways: perspectives of patients and healthcare professionals on addressing patient needs. Adaptive pathways workshop, European Medicines Agency, London, 8 December 2016.
-Regulatory perspectives on clinical outcomes and role of surrogate markers.Pan tumor scientific exchange meeting. Rome 9-10 February 2017.
-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.
-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.
-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
-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.
-Challenges in regulation. Special Symposium: access to innovative drugs in the EU. ESMO Annual Congress, Madrid 8-12 September 2017.
-Discussant of abstacts 1400-41-42 at the Poster Discussion session-Public Health Policy and Health Economics. ESMO Annual Congress, Madrid 8-12 September 2017.
-Adaptive pathways and innovative medicines development for improved access. Panel discussion. Value, Access and regulatory strategy workshop.25-26 October, Basel, Switzerland.
-Evolution of product development to respond to the future needs. Panel discussion. Value, Access and regulatory strategy workshop.25-26 October, Basel, Switzerland.
-Workshop on Site and Histology Independent Indications in Oncology.
Panel Discussion 5. EMA, London 14-15 December 2017