MEDICAL ONCOLOGY DEPARTMENT

DIRECTOR OF DEPARTMENT

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UNITS

HEMATOLOGY AND ALLOGENEIC BONE MARROW TRANSPLANTATION (ETMO) Paolo Corradini

> MEDICAL ONCOLOGY I Filippo de Braud (since August 1st)

> MEDICAL ONCOLOGY 2
> Alessandro M. Gianni

PEDIATRIC ONCOLOGY

Maura Massimino

ADULT SARCOMA MEDICAL TREATMENT Paolo G. Casali

HEAD AND NECK CANCER
MEDICAL ONCOLOGY
Lisa Licitra

MEDICAL DAY HOSPITAL Roberto Buzzoni



The Department consists of clinical medical Units (8 l beds), one centralized day hospital (28 beds), 22 outpatient rooms, and a laboratory area for clinical cell manipulation, flow cytometry, clinical pharmacology, and molecular biology. The routine clinical activity is focused on the treatment of adult and pediatric patients with solid tumors and hematologic malignancies. Several clinical programs are active, which range from conventional chemotherapy to phase I studies to the transplantation of hematopoietic cells.

The Department is organized in Units which are in charge of different aspects of cancer research and treatment.

- Medical Oncology 1: gastrointestinal and lung tumors, melanoma, renal, and prostate cancers and breast carcinomas; treatment and development of new drugs
- Medical Oncology 2: preclinical and clinical activities mainly in the field of malignant lymphomas and germ cell tumors
- Pediatric Oncology: pediatric patients with solid cancers
- Hematology and Allogeneic Bone Marrow Transplantation: treatment of hematologic malignancies and allogeneic transplantation.
- Adult Sarcoma Medical Treatment: clinical research activities in sarcomas and peritoneal mesothelioma
- Head and Neck Cancer Medical Oncology: clinical activity in head and neck carcinomas
- The Medical Day Hospital deals with adult patients referred by the clinical Units of the Department; diagnosis, treatment, and follow-up neuroendocrine tumors
- The Cardiology/Pneumology and Psychology Units cover all aspects of patients in their specific setting (see Shared Resources page 139).

hematology and allogeneic bone marrow transplantation (ETMO)

The ETMO Unit coordinates and takes part in several clinical trials testing new combinations of drugs and monoclonal antibodies for the treatment of lymphoid and myeloid malignancies with the aim of enhancing antitumor activity while reducing toxic effects. Several new trials have been started:

- a Phase III randomized trial comparing the efficacy of G-CHOP versus R-CHOP in previously untreated patients with CD20-positive DLBCL;
- a randomized phase III study to compare bortezomib, melphalan, prednisone (VMP) with high dose melphalan followed by bortezomib, lenalidomide, dexamethasone (VRD) consolidation, and lenalidomide maintenance in patients with newly-diagnosed multiple myeloma;
- Phase I study of a new protein kinase C inhibitor in patients with CD79-mutant diffuse large B-cell lymphoma. The Unit has also focused on:
- a phase I/II study of pomalidomide, cyclophosphamide, and prednisone (PCP) in patients with multiple myeloma relapsed and/or refractory to lenalidomide;

• a phase III trial for multiple myeloma patients at first relapse aimed at comparing the activity of a regimen including either bortezomib or lenalinomide combined with cyclophosphamide and dexamethasone. The study includes a biological portion aimed at the evaluation of simple biomarkers that may be useful to predict long term response in the relapse setting.

Other research projects include phenotypic, functional and molecular characterization of post-transplant T-cell and B-cell recovery to elucidate the kinetics of the immune reconstitution after stem cell transplantation, prospective analysis of the plasma miRNA profile of allografted patients to identify markers predictive of acute GVHD (aGVHD), onset analysis of the effects of myeloid-derived suppressor cells (MDSCs), dose contained in the graft on the incidence of GVHD use of a mouse model of peripheral T-cell lymphomas (PTCLs), and test in vivo the activity of new drugs and drug combinations.

Keywords: lymphoma, transplantation, myeloma

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HEALTHCARE ASSISTANTS Carmelo Fede, Evelina Palella, Jose Noboa Velasco, Nunzio Bovello



RELEVANT NOTES

Publications

Barosi G, Bosi A, Abbracchio MP, Danesi R, Genezzani A, Corradini P, Pane F, Tura S. Key concepts and critical issues on epoetin and filgrastim biosimilars. A position paper from the Italian Society of Hematology, Italian Society of Experimental Hematology, and Italian Group for Bone Marrow Transplantation. Haematologica. 2011; 96: 937-42.

Corradini P, Sarina B, Farina L. Allogeneic transplantation for Hodgkin's lymphoma. Br J Haematol. 2011; 152: 261-72.

Thiel U, Wawer A, Wolf P, Badoglio M, Santucci A, Klingebiel T, Basu O, Borkhardt A, Laws HJ, Kodera Y, Yoshimi A, Peters C, Ladenstein R, Pession A, Prete A, Urban EC, Schwinger W, Bordigoni P, Salmon A, Diaz MA, Corradini P, et al. No improvement of survival with reduced-versus high-intensity conditioning for allogeneic stem cell transplants in Ewing tumor patients. Ann Oncol. 2011; 22: 1614-21.

In 2011, the previous two Divisions of Medical Oncology managing most solid tumors were merged under the direction of Dr Filippo de Braud since August 1, as it was when Gianni Bonadonna was leading Medical Oncology in our Institute. Our mission is to improve clinical care and outcomes of medical treatment of cancer through multidisciplinary management, personalized medicine, and development of new drugs and strategies. A major effort has been made to restore the infrastructure for inpatient care and renew the clinical research structure. Major areas of interest are:

- Translational research on prognostic and/or predictive biomarkers in most solid tumors (upper and lower gastrointestinal tract, non-small cell lung cancer, malignant pleural mesothelioma, and thymoma).
- New generation targeted therapy and immunotherapy for malignant melanoma.
- Adjuvant and systemic treatment of patients affected by renal cell carcinoma and the management of castration-resistant prostate cancer using new therapeutic approaches.
- The identification and selection of different subsets of

breast cancer patients to be treated differently according to the molecular profile of their disease (i.e. integrating targeted therapies with standard chemotherapy or with hormone treatment).

- · Active involvement in research on antiemetic drugs.
- A unit fully dedicated to new drug development (phase I and Ib studies) and the promotion of translational research projects. In this regard, we propose not only to develop treatments using new molecular compounds, but also to investigate new therapeutic strategies.

The facilities available at Medical Oncology include a 22 bed inpatient ward, a day hospital area, 9 consulting rooms (one of which is dedicated to consultations and first-admittance visits), and a research laboratory for pharmacokinetic and pharmacodynamic evaluation of new treatments. In 2011, the Unit carried out 37,387 clinical visits, 458 consultations to patients at first access; 2 phase I, 6 phase II, and 5 phase III trials were activated in the last quarter of 2011.

Keywords: patient care, new drug development, personalized medicine

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RELEVANT NOTES

Collaborations

The clinical research activities stem from the productive collaboration with different institutes and cooperative groups. OM I has a long-standing collaboration with the Breast Cancer Working Group of the Michelangelo Foundation aimed at the conduct and the coordination of Phase II/III trials in operable breast cancer or metastatic disease. The collaboration with the Southern Europe New Drugs Organization is focused on Phase I and early Phase II studies in breast cancer and all solid tumor types.

Publications

Del Vecchio M, Mortarini R, Tragni G, Di Guardo L, Borsani I, Di Tolla G, Agustoni F, Colonna V,

Weber JS, Anichini A.T-cell activation and maturation at tumor site associated with objective response to ipilimumab in metastatic melanoma. J Clin Oncol. 2011; 29: e783-8.

Procopio G, Guadalupi V, Giganti MA, Mariani L, Salvioni R, Nicolai N, Capone F, Valdagni R, Bajetta E. Low dose of ketoconazole in patients with prostate adenocarcinoma resistant to pharmacological castration. BJU Int. 2011; 108: 223-7.

Contributions

The Unit, together with other important members of the multidisciplinary team, was asked by ROL (Rete Oncologica Lombarda) to update national guidelines. Prof. de Braud and Dr. Del Vecchio were involved in drafting the MELANOMA guidelines (AIOM).

medical oncology 2

Medical Oncology 2 Unit carries out both preclinical and clinical translational research in a variety of fields, including hematopoietic stem cells, immunotherapy, autologous stem cell transplantation (ASCT), and targeted therapies. The Unit includes four areas (a 12-bed inpatient ward; a day hospital facility; an outpatient clinic with three consulting rooms; a cell processing laboratory) and provides care mainly for patients with non-Hodgkin lymphomas (NHL), Hodgkin lymphoma (HL), multiple myeloma, and selected patients with high-risk germ cell testicular tumors. During 2011, an average of 150 patients were treated as inpatients, resulting in a total of 500 admissions, and 35 patients received ASCT. A total of 1500 treatments were administered in day hospital. An average of 300 new outpatients requested examination. The activity of the cell processing laboratory consisted of 1100 CD34+ cell monitoring and 220 stem cell cryopreservations.

The following phase II and III studies have been launched from our Unit:

- phase III study comparing rituximab-ABVD and ABVD followed by involved-field radiotherapy in early-stage HL
- phase II trial evaluating of atumumab, bendamustine, and dexamethasone in elderly patients with mantle cell NHL
- phase II trials investigating efficacy and safety of epigenetic and targeted therapies in relapsed/refractory lymphomas.

A randomized phase III trial in advanced stage HL patients receiving ABVD or BEACOPP as first-line chemotherapy has been concluded and its results have been published in the New England Journal of Medicine. Two randomized phase III clinical studies comparing standard- and high-dose chemotherapy in aggressive NHL and chronic lymphocytic leukemia have been concluded. In the preclinical area, we identified HSP105 as a novel NHL tumor antigen whose expression was higher in aggressive NHL. Studies in mice suggest inhibiting HSP105 could help treat B cell NHL. Developing new anti-HSP105 therapeutic monoclonal antibodies is ongoing.

Keywords: lymphoproliferative disease, stem cell transplantation, immunotherapy

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RELEVANT NOTES

Collaborations

Istituto Superiore di Sanità (ISS), Rome, Italy; Cancer Centers of Federazione Italiana Linfomi (FIL); Istituto di Ematologia "Seragnoli", University of Bologna, Italy; Department of Hematology, University of Turin, Italy; MD Anderson Cancer Center: Houston, Texas, USA

Publications

Viviani S, Zinzani PL, Rambaldi A, Brusamolino E, Levis A, Bonfante V, Vitolo U, Pulsoni A, Liberati AM, Specchia G, Valagussa P, Rossi A, Zaja F, Pogliani EM, Pregno P, Gotti M, Gallamini A, Rota Scalabrini D, Bonadonna G, Gianni AM; Michelangelo Foundation; Gruppo Italiano di Terapie Innovative nei Linfomi; Intergruppo Italiano Linfomi. ABVD versus BEACOPP for Hodgkin's lymphoma when high-dose salvage is planned. N Engl J Med. 2011; 365: 203-12.

Zappasodi R, Bongarzone I, Ghedini GC, Castagnoli L, Cabras AD, Messina A, Tortoreto M, Tripodo C, Magni M, Carlo-Stella C, Gianni AM, Pupa SM, Di Nicola M. Serological identification of HSP105 as a novel non-Hodgkin lymphoma therapeutic target. Blood. 2011; 118: 4421-30.

Brain tumors. The Division is the national coordinator for trials in localized medulloblastoma that are in the pipeline. Coordination continues for the second national study on ependymoma (129 patients) for the European protocol.

Brain stem gliomas. A pilot study with concomitant radiotherapy, anti-EGFR nimotuzumab and vinorelbine has accrued 21 patients demonstrating an improvement with previous results in PFS and OS.

Neuroblastoma. The Division has the national coordination of the pan-European protocol for high-risk neuroblastoma; over 370 Italian patients have been enrolled so far (51 by our unit).

Wilms tumor. The Division chairs the national Working Group for clinical and biological studies, and also chairs the relapse program.

Soft-tissue sarcomas. Accrual for the EpSSG trials (cocoordinated by one of us) is ongoing: 2010 patients from 16 different countries, 212 from our center, the highest accrual

Rare childhood tumors. The Division co-coordinates a national-scale cooperative project for the most uncom-

mon pediatric cancers. Since the project started, 600 patients have been enrolled (one third from our center). A European Network has been established on rare tumors, called EXPeRT (European Cooperative Study Group on Pediatric Rare Tumors): a member of our center co-coordinates the group.

Bone tumors. A new protocol for localized limb osteosarcoma has been launched, including mifamurtide for adverse biological features.

Germ-cell malignancies. The Unit is the national coordinator for this trial.

New drugs. A phase I "first-in-child" trial with LDE225 (anti-SMO) and two front-line randomized trials in metastatic sarcoma and high-grade glioma with bevacizumab.

Board member of Pan-European Network for Care of Survivors after Childhood and Adolescent Cancer (Pan-Care) Adolescents. Our center leads the AIEOP national Working Group. A Youth Project has been recently launched by our Unit.

Keywords: international trials, new drugs, adolescents

HEAD

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Barbara Giacon, psychologist

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RELEVANT NOTES

Collaborations

AlEOP (Associazione Italiana di Ematologia Oncologia Pediatrica); SIOP (International Society for Pediatric Oncology) COG (Children Oncology Group) ISG (Italian Sarcoma Group)

Publications

Chosen among the over 30 already published:

Ferrari A, Miceli R, Rey A, Oberlin O, Orbach D, Brennan B, Mariani L, Carli M, Bisogno G, Cecchetto G, De Salvo GL, Casanova M, Vannoesel MM, Kelsey A, Stevens MC, Devidas M, Pappo AS, Spunt SL. Non-metastatic unresected paediatric non-rhabdomyosarcoma soft tissue sarcomas: results of a pooled analysis from United States and European groups. Eur J Cancer. 2011;

Massimino M, Gandola L, Barra S, Giangaspero F, Casali C, Potepan P, Di Rocco C, Nozza P, Collini P, Viscardi E, Bertin D, Biassoni V, Cama A, Milanaccio C, Modena P, Balter R, Tamburrini G, Peretta P, Mascarin M, Scarzello G, Fidani P, Milano GM, Sardi I, Genitori L, Garrè ML. Infant ependymoma in a 10-year AIEOP (Associazione Italiana Ematologia Oncologia Pediatrica) experience with omitted or deferred radiotherapy. Int J Radiat Oncol Biol Phys. 2011; 80: 807-14.

Contributions

Eupolis Master for Hospital Management (M. Massimino) Editor of the book: D. Schneider, I. Brecht, T. Olson, A. Ferrari. Rare tumors in children and adolescents. Springer (with many contributors in the Unit).



adult sarcoma medical treatment

This Medical Oncology Unit deals with adult patients with sarcomas and peritoneal mesothelioma within the institutional Multidisciplinary Sarcoma Group.

In 2011, the Unit had more than 450 inpatient admissions and over 5000 outpatient visits, with more than 1000 new sarcoma patients seen. About 600 new sarcoma patients were clinically shared with other Italian centers through the Italian Network on Rare Cancers (RTR), a project aimed at distantly sharing cases of adult patients with rare solid cancers to improve the quality of care and reduce patient migration.

The Unit has always had a strong focus on networking. In addition to coordinating the national project of RTR, it coordinates the rare cancer area of the Rete Oncologica Lombarda (ROL), the cancer network of Lombardy Region. The Unit also submitted a project to create a virtual center on mesenchymal neoplasms in collaboration with RTR and ROL by joining some centers in the Milan area. From 2012, this should result in a highly strengthened sarcoma facility in the Milan area, with the potential of serving as one of the main reference centers for sarcomas in Europe.

The Unit was involved in driving the update of the ESMO Clinical Guidelines on STS and GIST and the Clinical Guidelines on Sarcomas and Rare Tumors within the Regional Cancer Network. Clinical research activities

included the participation in 37 prospective clinical studies on sarcomas, with 60 patients enrolled in 2011. Among others, the Unit was the first enrolling center in the international trial on regorafenib in advanced pre-treated GIST; it coordinates the medical therapy of the Italian Sarcoma Group trial on neoadjuvant histology-driven chemotherapy of high-risk soft tissue sarcomas; it coordinates a study in imatinib resistant-chordomas on imatinib + everolimus. In 2011, among others, the Unit published significant contributions to further understand the role of trabectedin and sunitinib in soft tissue sarcomas. It co-signed the general report of the RARECARE project, which finalized a clinically and epidemiologically sound definition of "rare cancers", also providing a "list" of them, with incidence, prevalence, and survival data in Europe. It co-signed the report of an important retrospective clinical/molecular/pathologic study on the natural history of

GIST. Other significant scientific papers were accepted and are due for publication in 2012, among others with regard to: a Phase 2 study on imatinib in chordoma, which the Unit coordinated after first reporting the efficacy of this targeted therapy in such a rare disease; the Italian Sarcoma Group trial on 3 vs. 5 cycles of neoadjuvant chemotherapy in high-risk soft tissue sarcomas; other reports on the histology-driven approach to soft tissue sarcomas.

Keywords: adult sarcoma, GIST, rare cancers

2011 RELEVANT NOTES

Publications

Casali PG, Sanfilippo R. Uterine sarcomas: a multidisciplinary challenge. Eur J Cancer 2011; 47 Suppl 3: S326-7.

Casali PG. Medical oncology: the long-awaited prize of recognition. Ann Oncol. 2011;22(8):1695-7.

Stacchiotti S, Casali PG. Systemic therapy options for unresectable and metastatic chordomas. Curr Oncol Rep. 2011: 13: 323-30.

Stacchiotti S, Palassini E, Sanfilippo R, Vincenzi B, Arena MG, Bochicchio AM, De Rosa P, Nuzzo A, Turano S, Morosi C, Dei Tos AP, Pilotti S, Casali PG. Gemcitabine in advanced angiosarcoma: a retrospective case series analysis from the Italian Rare Cancer Network Ann Oncol. 2012; 23(2):501-8.

Italiano A, Laurand A, Laroche A, Casali P, Sanfilippo R, Le Cesne A, Judson I, Blay JY, Ray-Coquard I, Bui B, Coindre JM, Nieto A, Tercero JC, Jimeno J, Robert J, Pourquier P. ERCC5/XPG, ERCC I, and BRCA I gene status and clinical benefit of trabectedin in patients with soft tissue sarcoma. Cancer. 2011; 117(15): 3445-56.

Stacchiotti S, Negri T, Zaffaroni N, Palassini E, Morosi C, Brich S, Conca E, Bozzi F, Cassinelli G, Gronchi A, Casali PG, Pilotti S. Sunitinib in advanced alveolar soft part sarcoma: evidence of a direct antitumor effect. Ann Oncol. 2011; 22(7): 1682-90

Sanfilippo R, Miceli R, Grosso F, Fiore M, Puma E, Pennacchioli E, Barisella M, Sangalli C, Mariani L, Casali PG, Gronchi A. Myxofibrosarcoma: Prognostic Factors and Survival in a Series of Patients Treated at a Single Institution. Ann Surg Oncol. 2011; 18: 720-5.

Contributions

Paolo G. Casali is: Member of the Executive Board of the European Society for Medical Oncology (ESMO) as Chair of the Public Policy Committee; Member of the Sarcoma Faculty of the European Society for Medical Oncology (ESMO); Member of the Policy Committee of the European Cancer Organization (ECCO); Secretary of the Italian Sarcoma Group; Member of the EORTC Soft Tissue and Bone Sarcoma Group; Coordinator of the Italian Network on Rare Tumors; Member of the Regional Oncology Commission, Regione Lombardia, Italy; Coordinator of the Rare Cancer Group of the Lombardia Oncology Network; Editor in chief of Clinical Sarcoma Research (http://www.clinicalsarcomaresearch.com)



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Data managers and administrative staff are shared with the Head and Neck Cancer Medical Oncology Unit The Unit performed the following clinical activities in 2011: 474 inpatient admissions, 75 day hospital admissions, and 3723 outpatient visits. In 2011, the following clinical trials were conducted: five studies were opened with 58 patients enrolled; five trials on thyroid cancer, nine on squamous head and neck cancer, one on salivary gland tumor, and one on basal cell carcinoma were active. The Unit was also involved in the establishment of the oncological network in Lombardy (ROL) for head and neck cancers.

Keywords: head and neck cancer, medical oncology, clinical research

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Data managers and administrative staff are shared with the Adult Sarcoma Medical Treatment Unit



RELEVANT NOTES

Collaborations

Lisa Licitra is a member of the board of the EORTC and chair-elect of the Head & Neck EORTC group

The Unit coordinates the START project.

Publications

Bossi P, Orlandi E, Bergamini C, Locati LD, Granata R, Mirabile A, Parolini D, Franceschini M, Fallai C, Olmi P, Quattrone P, Potepan P, Gloghini A, Miceli R, Mattana F, Scaramellini G, Licitra L. Docetaxel,

cisplatin and 5-fluorouracil-based induction chemotherapy followed by intensity-modulated radiotherapy concurrent with cisplatin in locally advanced EBV-related nasopharyngeal cancer. Ann Oncol. 2011; 22(11): 2495-500.

Granata R, Miceli R, Orlandi E, Perrone F, Cortelazzi B, Franceschini M, Locati LD, Bossi P, Bergamini C, Mirabile A, Mariani L, Olmi P, Scaramellini G, Potepan P, Quattrone P, Ang KK, Licitra L. Tumor stage, human papillomavirus and smoking status affect the survival of patients with oropharyngeal cancer: an Italian validation study. Ann Oncol. 2011

Contributions

Lisa Licitra is:

Associate Editor, Annals of Oncology Chair Head and Neck faculty for ESMO

The Unit is responsible for the production and updating of guidelines for head and neck cancer.

medical day hospital

The Day Hospital and Oncologic Outpatient Therapy Unit (MDH) treats adult patients referred by different clinical Units of the Department. The complexity of some oncologic medical treatments and the increasing number of medical trials frequently require close observation during treatment and one day hospitalization. Treatments are prepared by specialized nurses who dilute therapeutic agents in a protected area equipped with two air flow cabinets, and administer them under the supervision of MDH physicians. A separate section is dedicated to short duration regimens or biological therapies by infusion pump systems and management of central venous catheters. Special care is given to management and prevention of emesis, diarrhea, extravasation of cytotoxic drugs, and acute drug reactions for which a project about pharmacovigilance (FARMAONCO) is ongoing. The referent physician of this regional project is Dr. Ferrari since 2009. The acute adverse effects are reported, with the help of Dr. Fanetti, in a database. A room in the outpatient clinic is dedicated to diagnosis, treatment, and

follow-up in patients diagnosed with neuroendocrine tumors (NET) and a database with all NET cases followed in our Institution is ongoing with the collaboration of Dr. Damato. Our Institution has been certified as a Center of Excellence by the European Society Neuroendocrine Tumors.

In 2011, the activity of MDH consisted in approximately 21,500 procedures (monthly average activity of 1800). 51% of these procedures were short therapies, 36% long therapies, 4% treatments requiring admission, and 9% were medical procedures (i.e. CVC medications, lumbar puncture, bone marrow biopsy). The cancer types treated were breast cancer (35%), gastrointestinal cancer (20%), hematologic malignancies (23%), melanoma (6%), lung cancer (8%), head and neck cancer (2.5%), sarcomas (1.5%), and other tumors (3%). Moreover, about 100 adverse drug reactions were reported during the year.

Keywords: medical procedures, adverse drug reactions, neuroendocrine tumors

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RELEVANT NOTES

Publications

Platania M, Agustoni F, Formisano B, Vitali M, Ducceschi M, Pietrantonio F, Zilembo N, Gelsomino F, Pusceddu S, Buzzoni R. Clinical retrospective analysis of erlotinib in the treatment of elderly patients with advanced non-small cell lung cancer. Target Oncol. 2011; 6(3): 181-6.

Procopio G, Verzoni E, Iacovelli R, Guadalupi V, Gelsomino F, Buzzoni R. Targeted therapies used sequentially in metastatic renal cell cancer: overall results from a large experience. Expert Rev Anticancer Ther. 2011: 11(11): 1631-40.

Contributions

Roberto Buzzoni is a member of the Editorial Board of Tumori

The Unit is in part responsible for the production and updating of NET guidelines of the ROL Clinical Guidelines

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