

704

CURRICULUM VITAE

Name: Emanuela Marrocco
Birth date: September 23, 1969

Education: 1988: High School Degree, Liceo Scientifico "G. Peano", Cinisello Balsamo
1997: Pharmacy Degree, University of Milan
09/1991-03/1992: Training for Pharmacy to Dr. Benaglio Chemist's in Cinisello Balsamo (MI)

Previous positions: 04/2006-30/04/2021: **Study Coordinator** at the Pediatric Division of Fondazione MBBM/ASST Monza(MB)

Main activities

Clinical Trial Start up:

- o Qualified Local Representative for Ethical Committee
- o Implementation of documentation for Protocol submission to Ethical Committee and competent authorities (AIFA-ISS)
- o Budget negotiation

Clinical Research Management:

- o Medical Staff activities coordination in order to guarantee GCP and Protocol compliance
- o Assistance during Monitoring visits and audits
- o SAE monitoring and reporting
- o CAR-T Clinical Trials Coordinating
- o Phase I Clinical Trial Coordinating

Experimental drug management:

- o Drug accountability, storage and dispensing

Data handling:

- o Data entry
- o data query resolution

05/1998-09/2000: **Data Manager/Study Coordinator Fellow** at the **Division of Medical Oncology**, European Institute of Oncology, Milan

10/2000-04/2001: **Data Manager/Study Coordinator Fellow** at the **Division of Hematoncology**, European Institute of Oncology, Milan

Main activities

Data handling:

- o CRF design
- o Database developing
- o Data entry
- o Source data verification and data queries generation
- o Data descriptive analysis, development of tables and survival plots.

Medical writing:

- Collaboration with Principal Investigator and Statistician in Study Protocol planning, clinical reports developing, scientific presentations and publication of results

Experimental drug management:

- Drug accountability and dispensing

Clinical Research Management:

- Interaction with Ethical Committee and administrative office
- Management of randomization processes
- Medical Staff activities administration in order to guarantee GCP compliance
- SAE monitoring and reporting

05/2001-07/2001: Clinical Trial Administrator at the Medical Market Company Italy, Pharmacia & Upjohn, Milan

Main activities

- Italian CRAs coordinating in International Studies
- Interaction with International Study Team
- Authorization requests preparing and forwarding to local Ethical Committee
- Interaction with legal and local administrative offices in developing financial agreements
- Drug supplies management
- Protocol Amendments and SAE reports forwarding to Italian Sites
- Relationship with Central Laboratories

09/2001-01/2006: Clinical Data Manager at the CRO OPISData, Desio, Milan

Main activities

- Drafts and designs the Case Report Form (CRF) according to the study protocol and Sponsor's specific standard forms.
- Prepares the CRF manual to support the Investigator in the correct completion of CRF.
- Documents all data management activities for the study in the Data Management Plan.
- Interacts with clinical database Administrator for any issue related to database structure.
- Provides conventions to be applied during data entry session.
- Gives training to data entry clerks on specific study.
- Assists data entry clerks in validation of data entered by single or double entry.
- Defines specifications for checking plausibility and consistency of data.
- Develops programs according to defined specifications in order to clean the data.
- Runs programs and identifies errors to be clarified at Investigator's site.

- Generates self explaining Data Query Forms (DQF) to be submitted to the Investigator and updates the database according to DQFs resolution.
- Ensures that CRFs and DQFs tracking is accurate.
- Provides coding of medical texts data according to international dictionaries with the support of medical expert.
- Carries out reconciliation of Serious Adverse Events as per the Sponsor's procedure.
- At the end of cleaning process declares that the study data base is clean and locks the data base.
- Interacts with monitors, statistician and medical adviser in the study team for any issues related to CRF preparation and data cleaning process.
- Updates his/her expertise by attending specific courses

Clinical Trial Experience

Start Date (YYYY)	Phase (I,II,III,IV)	Indication
1996-2000	I,II,III	Solid Tumors
2000-2001	I,II,III	Haematology, Bone Marrow Transplantation
2001	II, III, IV	Oncology, Cardiovascular, Infectious Diseases, Genitourinary
2001-2006	II, III, IV	Oncology, Cardiovascular, Infectious Diseases, Genitourinary, Other Diseases
2006-2018	I-II, III, IV	Paediatric Haematological Diseases, HSCT, Rare diseases, Gastro-intestinal, Infectious, Neonatology, Obstetric

Relevant training

10/1998: GIDM (Gruppo Italiano di Data Manager) Meeting, Azienda Ospedaliera of Parma

12/1998: ACES® (Automated Clinical Evaluation System) course at SENDO (South Europe New Drug Organization), Milan

04/1999: GIDM Meeting 'II Data Manager: realtà italiana ed europea a confronto', Forlì

05/2000: EORTC course on 'Clinical Trial Statistics for Non Statisticians', Brussels

06/2000: 2nd Milan Breast Cancer Conference, Milan

06/2000: IBCSG (International Breast Cancer Study Group) Annual Meeting, Milan

01/2001: 'Oral Levofloxacin as prophylaxis for bacterial infections in neutropenic patients: a randomized, placebo-controlled, double-blind, multicenter trial' Investigators' Meeting, Roma

10/2001: Microsoft ACCESS course, OPIS Data, Desio

03/2002: GLIVEC/GIST Study CSI571BIT03 Investigator's Meeting, oral presentation at the 'CRF presentation and completion' session, Camogli

07/2002: SAS Base/Listing course, OPIS Data, Desio

04/2003: Clinical Data Management course, OPIS Data, Desio

06/2003: GIDM Meeting 'Studi osservazionali e di fase IV', Genova

07/2003: SAS Procedures and Macro facilities course, OPIS Data, Desio

February 2010: Teacher on the lesson: "LE SPERIMENTAZIONI CLINICHE CONTROLLATE IL CONSENSO INFORMATO"
Master Scienze Infermieristiche Pediatriche
UNIVERSITA' STUDI DI MILANO BICOCCA

24/09/2010: Speaker at the AIEOP (Associazione Italiana Ematologia Oncologia Pediatrica) course "Nuovi farmaci in oncologia pediatrica, dalla ricerca ai trials clinici", Università Cattolica del Sacro Cuore di Roma

October 2010: Rejuvenation Investigator Meeting Dasatinib
CA180226, Uffici Bristol Myers Squibb, Roma

30/11/2010: Annual Meeting 'La realizzazione degli studi clinici in oncologia, : dal disegno alla raccolta del dato. Incontro di aggiornamento Novartis, Milano

February 2011: Teacher on the lesson: LE SPERIMENTAZIONI CLINICHE CONTROLLATE IL CONSENSO INFORMATO
Master Scienze Infermieristiche Pediatriche
UNIVERSITA' STUDI DI MILANO BICOCCA

30/10/2012: 'The Way We Work' Quarto incontro di aggiornamento: Novartis e i Centri Sperimentali insieme per la qualità e l'innovazione nella ricerca clinica, Milano

12-13/11/12: Investigators' Meeting Protocol Roche
NV25719 'Oseltamivir in Immunocompromized Children', Vienna, Austria

May 2013: Teacher on the lesson: LE SPERIMENTAZIONI CLINICHE CONTROLLATE IL CONSENSO INFORMATO
Master Scienze Infermieristiche Pediatriche
UNIVERSITA' STUDI DI MILANO BICOCCA

October 2013: Speaker at the AIEOP (Associazione Italiana Ematologia Oncologia Pediatrica) Working Group on Farmacologia Clinica e Farmacosorveglianza 'Sperimentazioni non commerciali e Comitati Etici: Novità'

26/06/2014 Transcelerate GCP Training Course

April 2015: Giornata di Studio "Dalla Regione all'Europa e dall'Europa alla Regione: il Regolamento europeo sulla sperimentazione clinica"
Palazzo Lombardia Milano

May 2015: Orphazyme Investigator Meeting Protocol CT-ORZY-NPC-001/002, 'CLINICAL DEVELOPMENT OF ARIMOCLOMOL IN NIEMANN-PICK DISEASE TYPE C'
Hotel Intercontinental de La Ville, Roma

December 2016: GCP NIDA Training Certificate

May 2018: Certificate of Attendance Transporting Dangerous Goods Training Provided by Mayo Medical Laboratories

June 2018: ICH GCP E6 (R2) Training Certificate

16/01/2019: II° Corso per Coordinatori di Ricerca Clinica: Gli studi clinici in oncematologia pediatrica: focus sul consenso informato. Policlinico Universitario Padova

15/05/2019: Advisory Board Novartis
Il ruolo del Trial Center nell'ambito degli studi clinici con CAR-T. Una Hotel, Milano
23-24/05/2019: PCYC-IM Study Coordinator & Pharmacist Training and Investigator Meeting
London

January /2020: Oral presentation at the Meeting 'La Ricerca clinica in Pediatria'
Padova

IT Knowledge:

Excellent knowledge of Microsoft Office
Good knowledge of SAS

Language:

Good English, Elementary French

Publication list:

Phase I dose-escalation study with weekly Taxol and Gemcitabine in patients with advanced non-small cell lung cancer: preliminary results.
T. De Pas, F. de Braud, C. Sessa, A. Sbanotto, C. Catania, M.G. Zampino, I. Minchella, S. Cinieri, M. Colleoni, F. Nolè, S. Ghilezan, E. Marrocco, A. Goldhirsh.
Paper, *Bullettin du Cancer*, 4, spt 1998, 179-183

Phase I and pharmacologic study of weekly gemcitabine and paclitaxel in chemo-naïve patients with advanced non-small-cell lung cancer.

T. De Pas, F. de Braud, R. Danesi, C. Sessa, C. Catania, G. Curigliano, S. Fogli, M. del Tacca, G. Zampino, A. Sbanotto, A. Rocca, S. Cinieri, E. Marrocco, A. Milani & A. Goldhirsh.
Paper, *Annals of Oncology* 11: 821-827, 2000

Vinorelbine, cisplatin and continuous infusion of 5-fluorouracil (ViFuP) in metastatic breast cancer patients: a phase II study.

F. Nolè, E. Munzone, M. Mandalà, C. Catania, L. Orlando, M.G. Zampino, I. Minchella, M. Colleoni, G. Peruzzotti, E. Marrocco, A. Goldhirsh.
Paper, *Annals of Oncology* 12: 95-100, 2001

Bone scan had no role in the staging of 765 consecutive operable T(1-2)N(0-1) breast cancer patients without skeletal symptoms.

Curigliano G, Ferretti G, Colleoni M, Marrocco E, Peruzzotti G, De Cicco C, Paganelli G, Goldhirsch A.
Paper, *Annals of Oncology* 12: 724-5, 2001

Phase I study of twelve-day prolonged infusion of high-dose ifosfamide and doxorubicin as first-line chemotherapy in adult patients with advanced soft tissue sarcomas.

De PT, Co G, Masci G, Catania C, Comandone A, Boni C, Tucci A, Paganì O, Marrocco E, de BF; Italian Sarcoma Group.
Paper, *Annals of Oncology* 13: 161-6, 2002

Phase II Trial of Vinorelbine, Cisplatin and continuous infusion of 5-Fluorouracil followed by hyperfractionated radiotherapy in locally advanced head and neck cancer.

Orecchia R, Jerezek-Fossa BA, Catalano G, Chiesa F, DePas T, Masci G, Krengli M, Vavassori A, De Paoli F, Robertson C, Marrocco E, De Braud F.
Paper, *Oncology* 2002;63(2):115-23

Combined Modality Treatment for Locally Advanced (LA)

Pancreatic Carcinoma (PC): ECF (Epirubicin, Cisplatin, Fluorouracil as Continuous Infusion) plus Concomitant Three-dimensional Conformal Radiotherapy (3D-CRT).
E. Munzone, F. de Braud, L. Orlando, R. Orecchia, F. Nolè, P. Tralongo, H. Marsiglia, R. Biffi, E. Marrocco and A. Goldhirsh.

Abstract: 35th annual meeting, ASCO, Atlanta, May 1999, Abs.1125

Dose-Finding Phase I Study with Weekly Taxol (T) and Gemcitabine (G) in Chemo-Naive Patients with Advanced non Small Cell Lung Cancer (NSCLC).

F. de Braud, T. De Pas, C. Sessa, A. Sbanotto, C. Catania, M.G. Zampino, S. Cinieri, T. Ghilenzan, F. Nolè, N. Fazio, I. Minchella, U. Pastorino, E. Marrocco and A. Goldhirsh.
Abstract: 35th annual meeting, ASCO, Atlanta, May 1999, Abs.1932

Primary Chemotherapy in Operable or Locally Advanced Breast Cancer (OLABC) Using a Regimen Containing Vinorelbine (V), Cisplatin (P) and Continuous Infusion of 5-Fluorouracil (Fuci).

I. Minchella, M. Colleoni, F. Nolè, M. Sarti, C. Catania, B. Ullrich, C. Greco, G. Peruzzotti, M. G. Zampino, E. Marrocco, A. Goldhirsh.
Abstract: 35th annual meeting, ASCO, Atlanta, May 1999, Abs.516

Vinorelbine, Continuous Infusion 5-Fluorouracil and Cisplatin (ViFuP) in Patients with Inoperable Head & Neck Carcinoma: A Regimen with a Low Toxicity Profile.
G. Masci, B. Ullrich, L. Orlando, A. Sbanotto, S. Ghilezan, E. Marrocco, G. Peruzzotti, T. De Pas, F. Nolè and F. de Braud.
Poster presentation: 1st Congresso Nazionale di Oncologia Medica 1999, Roma, October 24-28 1999, Abs.246

Primary Chemotherapy in Operable or Locally Advanced Breast Cancer (OLABC) Using a Regimen Containing Vinorelbine (V), Cisplatin (P) and Continuous Infusion of 5-Fluorouracil (Fuci).
I. Minchella, F. Nolè, M. Sarti, G. Peruzzotti, M. Colleoni, L. Orlando, E. Munzone, E. Marrocco, M. G. Zampino and A. Goldhirsh.
Poster presentation: 1st Congresso Nazionale di Oncologia Medica 1999, Roma, October 24-28 1999, Abs.188

Phase I study of vinorelbine (V) and capecitabine (C) in advanced breast cancer (ABC).
F. Nolè, C. Catania, M. Mandalà, E. Munzone, A. Rocca, G. Zampino, I. Minchella, C. Noverasco, M. Colleoni, E. Marrocco, A. Lambiasi, A. Goldhirsch.
Poster presentation: 36th Annual Meeting, ASCO, New Orleans May 20-23 2000, Abs. 428

Vinorelbine, continuous infusion 5-fluorouracil and cisplatin (ViFuP) in patients with inoperable head & neck carcinoma: a regimen with a low toxicity profile.
G. Masci, F. Chiesa, R. Orecchia, L. Calabrese, B. Fossa-Jereckz, M. Ansarin, V. Gebbia, E. Marrocco, F. Nolè, T. De Pas, G. Ferretti, F. de Braud.
Poster presentation: 36th Annual Meeting, ASCO, New Orleans May 20-23 2000, Abs. 1694N

Phase I Study of Gemcitabine (GEM) and Paclitaxel (TAX) in Chemo-Naive Patients with Advanced Non-Small Cell Lung Cancer (NSCLC).
Tommaso M De Pas, Romano Danesi, Cristiana Sessa, Chiara Catania, Stefano Fogli, Giuseppe Curigliano, Mario del Tacca, Giulia Zampino, Emanuela Marrocco, Alessandra Milani, Filippo de Braud.
Abstract: 36th Annual Meeting, ASCO, New Orleans May 20-23 2000, Abs. 2094

Cisplatin, Vinorelbine and continuous infusion fluorouracil (ViFuP) followed by sequential radiotherapy in inoperable locally advanced head and neck carcinoma (LA-HNC).
Giovanna Masci, Emanuela Marrocco, Fausto Chiesa, Giocchino Giuliano, Roberto Orecchia, Giuseppe

Curigliano, Chris Robertson, Franco Nolè, Barbara Jerezek-Fossa, Gianpiero Catalano and Filippo de Braud.
Poster presentation, AIOM 2000, Abs. A28

Intrathecal chemotherapy in carcinomatous meningitis from breast cancer.
Laura Orlando, Giovanni Martinelli, Nicola Fazio, Tommaso De Pas, Rossella Graffeo, Giulia Peruzzotti, **Emanuela Marrocco**, Saverio Cinieri, Aron Goldhirsch.
25th ESMO Congress, Hamburg, Germany, 13-17 October 2000, Abs. 703P

Phase II study of continuous infusion 5-fluorouracil, vinorelbine and cisplatin (ViFUP) in combination with sequential hyperfractionated radiotherapy in locally advanced head and neck carcinoma.
Giovanna Masci, F. Chiesa, G. Giuliano, R. Orecchia, **E. Marrocco**, G. Curigliano, C. Robertson, F. Nolè, B. Fossa-Jereckz, G. Catalano and F. de Braud.
25th ESMO Congress, Hamburg, Germany, 13-17 October 2000, Abs. 413P

Phase I study of vinorelbine (V) and capecitabine (C) in advanced breast cancer (ABC).
Franco Nolè, Chiara Catania, Mario Mandalà, Maria G. Zampino, Elisabetta Munzone, Gianluigi Ferretti, Giuseppe Curigliano, **Emanuela Marrocco**, Antonio Lambiase and Aron Goldhirsch.
23rd Annual San Antonio Breast Cancer Symposium, December 6-9, 2000, San Antonio, Texas, Abs. 550025

Radioterapia bifrazionata (bidRT) preceduta da chemioterapia di induzione con Vinorelbina (VNR), Cisplatino (CDDP) e fluorouracile (5-FU) nei tumori della testa collo localmente avanzati (LAHNC): esperienza dell'Istituto Europeo di Oncologia.
C. Bocci, B. Jerezek-Fossa, G. Catalano, A. Morra, F. De Braud, G. Masci, A. Vavassori, M. Ansarin, F. De Paoli, **E. Marrocco**, R. Orecchia
X Congresso AIRO, Pisa, 8-11 ottobre 2000

Vinorelbine (VNR), Cisplatin (CDDP) and continuous infusion fluorouracile (FU) followed by bifractionated radiotherapy (bidRT) in locally advanced head and neck cancer (LAHNC).
B. Jerezek-Fossa, G. Catalano, F. de Braud, G. Masci, F. Chiesa, F. De Paoli, A. Vavassori, **E. Marrocco**, C. Robertson, R. Orecchia.
Poster workshop: 19th Annual ESTRO Meeting, September 19-23, 2000, Istanbul, Turkey. Abs. 268

Multicicle sequential high dose chemotherapy (HDCT) as front line treatment in advanced epithelial ovarian cancer (AOC): preliminary results
F. Peccatori, N. Colombo, C. Griso, F. Pasini, A. Dicorato, R. Sabbioni, S. Cinieri, L. Lanata, E. Dolcini, E. Coccorocchio, **E. Marrocco**, G. Martinelli.

Oral presentation, 27th Annual Meeting European Group for Blood and Marrow Transplantation, Maastricht, The Netherlands, March 25-28, 2001, Abs. 589

High dose chemotherapy (HDCT) with idarubicin and melphalan and Peripheral Blood Stem Cell (PBSC) transplantation in patients with poor risk or relapsed high grade non Hodgkin lymphoma

G. Martinelli, R. Pastano, A. Alietti, E. Cocorocchio, A. Vanazzi, E. Marrocco, C. Corsini, F. Bertolini, S. Cinieri, P.F. Ferrucci, R. Scalamogna, A. Dicorato, F. Peccatori

Abstract: 27th Annual Meeting European Group for Blood and Marrow Transplantation, Maastricht, The Netherlands, March 25-28, 2001

Treatment of high risk of refractory follicular-lymphocytic lymphoma with 2-CDA and high dose chemotherapy (HDCT) with autologous peripheral blood stem cells (PBSC)

Martinelli, R. Scalamogna, E. Marrocco, P.F. Ferrucci, C. Rabascio, P. Mancuso, R. Pastano, A. Dicorato

Abstract: 27th Annual Meeting European Group for Blood and Marrow Transplantation, Maastricht, The Netherlands, March 25-28, 2001, Abs. 717

Continuing Preoperative Chemotherapy into the Perioperative Period for Patients with Operable Breast Cancer

Giuseppe Curigliano, Marco Colleoni, Gianluigi Ferretti, Laura Orlando, Chris Robertson, Emanuela Marrocco, Aron Goldhirsch.

Abstract: 37th ASCO Annual Meeting, San Francisco May 12-15, 2001, Abs 1785

Multicycle sequential high dose chemotherapy (HDCT): An Effective Regimen as First Line Treatment in Poor Prognosis Advanced Epithelial Ovarian Cancer (AOC)

Fedro Peccatori, Nicoletta Colombo, Claudia Griso, Felice Pasini, Gabriella Parma, Renata Sabbioni, Saverio Cinieri, Luigi Lanata, Emilia Cocorocchio, Emanuela Marrocco, Alessandra Alietti, Rocco Pastano, Enrica Dolcini, Giovanni Martinelli.

Poster Discussion, 37th ASCO Annual Meeting, San Francisco May 12-15, 2001, Abs. 818

Hepatic intra-arterial chemotherapy using a percutaneous catheter in pretreated patients with metastatic colorectal carcinoma.

Fazio N1, Orsi F, Grasso RE, Ferretti G, Medici M, Rocca A, Zampino G, Curigliano G, De Pas T, Colleoni M, Bonomo G, Marrocco E, Lunghi L, De Braud E.

Paper, *Anticancer Res.* 2003 Nov-Dec;23(6D):5023-30.

Glutamine-Enriched Nutrition Does Not Reduce Mucosal Morbidity or Complications After Stem-Cell Transplantation for Childhood Malignancies: A Prospective Randomized Study

Cornelio Uderzo, Paola Rebora, Emanuela Marrocco, Stefania Varotto, Francesca Cichello, Maurizio Bonetti, Natalia Maximova, Davide Zanon, Franca Fagioli, Francesca

Nesi, Roberto Masetti, Attilio Rovelli, Roberto Rondelli, Maria
Grazia Valsecchi, and Simone Cesaro
Parer, Transplantation Volume 91, N 12, June 27, 2011

I AUTHORIZE THE PROCESSING OF MY PERSONAL DATA ACCORDING TO
ART. 13 OF DL 196/2003 AND ART. 13 OF GDPR 679/16

Emanuele Maricchi 07/07/2021