Curriculum vitae

Mariangela Bruccoleri

PERSONAL DATA
First name: Mariangela
Last name: Bruccoleri

EDUCATION

2013, July 25th: Graduation in Biological Science at the University of Rome, La Sapienza, obtained with score 97/110. The thesis, entitled "Telomeres and their role in neurodegenerative diseases" describes the role of telomere shortening in Alzheimer and Parkinson's diseases.

Now: Student in Biology (Master Degree), at the University of Milan, Università degli studi Milano Bicocca.

2013 October / 2013 December: free collaboration with Fondazione IRCCS Ca'Granda Hospital in Milan (Gastroenterology Department) as Data Manager/Study Coordinator.

2014 February/ 2014 December: Research Grant with title "Identification of genetic polymorphisms associated with risk of hepatocellular carcinoma in patients with chronic viral hepatitis" in Fondazione IRCCS Ca' Granda Hospital in Milan (Gastroenterology Department) as Data Manager/Study Coordinator.

2015 Genuary/2015 December: Research Grant with title "Breath test with Aminopyrine in patient with HCV related cirrosis undergone to antiviral therapy interferone free" in Fondazione IRCCS Ca' Granda Hospital in Milan (Gastroenterology

Departement) as Data Manager/Study Coordinator.

2016 Genuary/2016 December: Research Grant with title "Effect of Proteasone and VEGF Receptor Inhibitors on NKG2D Ligand Expression on Hepatocellular Carcinoma Cells: Implications for Immunotherapy of Liver Cancer" in Fondazione IRCCS Ca' Granda Hospital in Milan (Multispecialist Units and Transplants Department) as Data Manager/Study Coordinator.

On April 2016, I participated in Continuing Medical Education courses (ECM): Emergency; Biologic Risk; Chemical Risk; Electrical Risk; Employees.

2017 Genuary/2017 December: research Grant with title "Rischio di Infezione da Virus dell' Epatite C Dopo Esposizione Professionale" in Fondazione IRCCS Ca' Granda Hospital in Milan (Gastroenterology and Hepatology Department) as Data Manager/Study Coordinator.

2018 Genuary/2018 December: research Grant with title: "Rischio di Infezione da Virus dell' Epatite C Dopo Esposizione Professionale" in Fondazione IRCCS Ca' Granda Hospital in Milan (Gastroenterology and Hepatology Department) as Data Manager/Study Coordinator.

WORK EXPERIENCES

Since February 2014, i worked in the Gastroenterology Department of the Fondazione IRCCS Ca' Granda Hospital in Milan, in the staff of Prof. Massimo Colombo until December 2016 and since Janaury 2017, i'm currently working in the Gastroenterology and Hepatology Department of Fondazione IRCCS Ca' Granda in Milan in the staff of Prof. Pietro Lampertico.
My activity includes the overall management of clinical studies : documents collection, data organization, verification of the source documents, CRF insertion and query solving , the use of the IXRS (Interactive Web/Voice Response System) for the drug assignment, the patients flowchart organization, and preparation of biological samples for delivery to central laboratories. I also carry out the continuous update and management of an internal database of

patients with chronic liver disease.
Since 2015 i'm currently inlvolving in managing agenda of Gastroenterology Department regarding procedures like Chemoembolization, Thermal Ablation, Radio-Embolization and related therapies to Hepatocellular Carcinoma.
Since 2016 i'm currenlty involving in organization of patients treated with Nexavar (collaboration with internal pharmacy and AIFA management)

SPECIFIC COMPETENCES AND KNOWLEDGE

SPECIFIC KNOWLEDGE OF LIVER NEOPLASTIC PARAMETERS:
During my activity on databases and clinical studies i had the opportunity to learn the main parameters useful to access the tumor conditions and chronic liver diseases (BCLC ,CHILD-PUGH, MELD score and Clip score), and also how to calculate it starting from the medical data.

DATABASE REALIZATION:
At Ca' Granda Hospital in Milan, i'm now responsible of a database containing the data of HCC patients (history of liver disease: diagnosis, etiology, clinical therapies, clinical trials; useful parameters to define the staging of the disease and to establish the survival of HCC patients). The database is currently realized in Excel.
I collaborated to making databases on alphafetoprotein studies, Interferon and DAA studies.
I also collaborated as co-author in realization of Abstract entitled "Serum markers for Early Diagnosis of HCC in HCV Cirrhotic Patients with SVR to DAA Treatment", submitted to AASLD 2017, and in realization of Abstract entitled "Changes of AFP and PIVKA-II Levels During DAA Treatment and Their Predictive Value for Early Diagnosis of HCC in HCV Cirrhotic Patients with SVR to DAA treatment" submitted to EASL 2018.

CLINICAL STUDIES:
I received ICH-GHP training during Investigator Meetings for clinical studies: 2533 METIV HCC Investigator Meeting Lisbon; Investigator Meeting for study protocol XL184-309; Investigator Meeting for 9785-CL-3021 Astellas.

I also received the following certifications:

-Investigator Site Training 4.6.2 (by PPD Electronic Data Capture on October 2013; (by Phase Forward training, on October 2013); (by Bayer GCP for Study Site Personnel; by Bayer Safety Fundamentals Oncology v1.6 on November 2013)
-Use of Electronic CRF (InForm GTM 5.5 Data Entry and Signature; Oracle Clinical RDC; meditata Rave
-Use of IVRS (IWRS, PPD; IRT On Demand 5.5 Site)
-Training on Rave and inspection readiness for clinical sites by Meditata University:
(Introduction to Rave EDC on Mar 2014; Rave Advanced Rave EDC for Site Users on Mar 2014; EDC Inspection Readiness for Clinical Sites on Mar 2014; Rave EDC Essentials for Clinical Research Coordinators on Mar 2014; EDC Inspection Readiness for Sponsors and CROs on Mar 2014).
-Training by Mayo Medical Laboratories / IATA 1.5 on June 2014 (Training for the shipping of Category A, Infectious substance affecting humans, category B, biological substance).
-Training by Mayo Medical Laboratories/ Transporting Dangerous Good on June 2014
-GCP (Good Clinical Practice)Training on November 2014 (Quintles)
-Intriduction to Rave EDC (08/sep/2015)
-Rave 5.6 Essentials for Clinical Research Coordinators (08/sep/2015)
-Rave EDC Essentials for Investigators with Data Entry (01/Jul/2016)
-Training for TransCelerate BioPharma on Dec 2016
-Updated training on April 2017: 1. Course Overview & Overview of ICH Good Clinical Practice; 2. Clinical Investogator Obligations & Qualification, Resources, IRBs/IECs; 3. Subject informed Consent &Protocol Compliance; 4. Investigational Product, Randomization, and Unblinding & Source Documents and CRF completion; 5. Safety Reporting, Financial Disclosure & Study Closeout, Trial Termination and Record Retention; 6. Non compliance, Scientific Misconduct and Fraud & Monitoring and Preparing for Audits and Inspection; 7. The European Clinical Trial Directives.
-Updated training for TransCelerate BioPharma on 11 Oct 2017
-GCP: A review of ICH E6, revision 2 changes for site personnel working on clinical research studies on NOV 2017

I've been involved in the following clinical studies:
"A Randomized, Double-blind, Multi-Center Phase 3 Study of ADI-

PEG 20 Plus Best Supportive Care (BSC) Versus Placebo Plus BSC in Subjects With Advamced Hepatocellular Carcinoma (HCC) Who Have Failed Prior System Therapy (Polaris Group)"

"A Phase 3, Randomized, Double-blind, Controlled Study of Cabozantinib (XL184) vs Placebo in Subjects with Hepatocellular Carcinoma Who have Received Prior Sorafenib (XL184-309)"

"A prospective, single-arm, multicenter, uncontrolled, open-label Phase II trial of refametinib (BAY 86-9766) in combination with sorafenib as first line treatment in patients with RAS mutant Hepatocellular Carcinoma (HCC)"

"A Randomized, Placebo-controlled, Double-blind, Multicenter Phase II Trial of Intravenous GC33 at 1600 mg Q2W in Previously Treated Patients with Unresecyable Advanced or Metastatic Hepatocellular Carcinoma (HCC)"- ROCHE, NP27884

"A Phase 3, Randomized, Double-Blind Study of Tivantinib (ARQ 197) in subjects with MET diagnostic-high inoperable Hepatocellular Carcinoma (HCC) treated with one prior systemic therapy"

"A Randomized Double-blind, Placebo-Controlled, Multicenter Phase III study of Regorafenib in patients with Hepatocellular Carcinoma (HCC) after Sorafenib (BAYER 15982)"

"Evaluation of Sorafenib in combination with local micro-therapy guided by GD-EOB-DTPA (Primovist) enhanced MRI in patients with inoperable HCC (SORAMIC)"

"A phase 2, Randomized, open label study to evaluate the efficacy, safety, pharmacodynamics, pharmacokinetics of the ANTI-ALK-1 MAB PF-03446962 in combination with BSC (best supportive care) vs. BSC alone in adult patients with advanced HCC (PFIZER A8471005)"

"A Randomized, global, double-blind, placebo controller, parallel group study to evaluate the efficacy and safety of once-daily oral Avatrombopag for the treatment of adults with thrombocytopenia associated with liver disease prior to an elective procedure (EISAI E5501-G000-311)"

"A Prospective, Randomized clinical trial on Yttrium-90 trans-

arterial radio-Embolization (Theraspere) vs standard of care (Sorafenib) for the treatment of HCC with portal vein thrombosis (YES-P TS-104)"

"Multicentre, randomized, controlled, open-label study comparing the efficacy and safety of slow repeated IV infusions of 2 doses of Doxorubicin Transdrug (20 mg/m2 or 30 mg/m2) to those of BSC in patients with HCC after failure or intolerance to Sorafenib (ReLive BA2011-/03/04)"

" A Multicenter, single arm, phase Ib/II study to evaluate efficacy, safety, and pharmacokinetics of MSC2156119J as monotherapy in subjects with Met+ HCC with Child Pugh Class A liver function who have failed Sorafenib treatment (MERCK EMR 200095-005)"

"Multicenter, Randomized Phase 2B Study to Evaluate the Efficacy, Safety and Tolerability of OCR-002 (ornithine phenylacetate) in Hospitalized Patients with Cirrhosis and Associated Hyperammonemia with an Episode of Hepatic Encephalopathy STOP-HE Study (OCERA Therapeutics, Protocol OCR002-HE209)"

"A Phase III, Randomized, Double Blind, Dummy-Controlled Study of ThermoDox® (Lyso-Thermosensitive Liposomal Doxorubicin-LTLD) in Hepatocellular Carcinoma (HCC) using standardized Radiofrequency Ablation (RFA) treatment time ≥ 45 minutes for solitary lesions ≥ 3 cm to ≤ 7 cm (Celsion Corporation)"

"A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Access teh Efficacy and Safety of Enzalutamide in Subjects with Advanced Hepatocellular Carcinoma (Astellas 9785-CL-3021)"

"A Phase 3 Randomised, Double-blind, Placebo-controlled Study to Access teh Safety and Efficacy of S-888711 (Lusutrombopag) for the Treatment of Thrombocytopenia in Patients with Chronic Liver Disease Undergoing Elective Procedures (L-PLUS 2)"

"Studio Osservazionale Prospettico, Multicentrico, No-profit, Farmacologico: Valutazione del disease outcome dopo clearance virale (SVR) in pazienti con cirrosi da HCV marginalmente compensati o scompensati trattati con antivirali diretti (DAAs) senza IFN"

"TATE vs TACE, An Open-Label Randomized Study Comparing

Transtarterial Tirapazamine Embolization vs Transarterial Chemoembolization In Intermediate Stage Hepatocellular Carcinoma (LT003)"

"Phase IIA Exploratory Study of Oral Milciclib Maleate in Patients with Unresectable or Metastatic Hepatocellular Carcinoma (CDKO-125a-010)"

"Studi sul genoma di HCC sviluppato in pazienti con Epatite C con SVR (HEPCASUS)"

"Studio osservazionale, longitudinale, di 5 anni della storia naturale e della gestione di pazienti affetti da carcinoma epatocellulare (TARGET-HCC)"

"A Phase III Clinical Trial of Intra-arterial TheraSphere® in theTreatment of Patients with Unresectable Hepatocellular Carcinoma (STOP-HCC)"

WORK ADDRESS:
Ospedale Maggiore Milano, Fondazione IRCCS Cà Granda
UOC Gastroenterologia ed Epatologia
Via Francesco Sforza, 35
20122 Milan

FOREIGN LANGUAGES
Enghish: Good (oral and written)

COMPUTER KNOWLEDGE

Operative system:
Windows 95/98 Good
XP Excellent
Vista Excellent
Mac OS Excellent

Office:
Word Excellent
Power Point Excellent
Excel Excellent
Open office:

Math Good
Base Good
Calc Excellent
Impress Excellent

Other applications:
Outlook Excellent
Internet Explorer Excellent
Google Chrome Excellent
Mozilla Firefox Excellent

Autorizzo il trattamento dei dati personali e la pubblicazione sul sito web della Fondazione, ai sensi della normativa vigente ed in particolare dell' art. 15 del d.lgs. n. 33 del 14 marzo 2013

(Mariangela Bruccoleri)

12 SETTEMBRE 2018
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