

PERSONAL INFORMATION

Alessandra Gambaro



ASST-Azienda Territoriale Socio Sanitaria, Monza

gambaro136@otmail.com**POSITION HELD****Senior Clinical Study Coordinator****DESIRED OCCUPATION**

Clinical start-up specialist
Country study manager
Clinical Project manager

• 05/2018 → now**Senior clinical study Coordinator***ASST, Monza via G.B Pergolesi, 20900 Monza- Malattie Infettive*

- Coordination and Data management of experimental Phase III Clinical Studies profit and no-profit in Infectious Disease in compliance with protocol, SOPs, GCPs.
- CRFs
- Participation and supporting in monitoring visits, pre-study and clos-out visits.
- Monitoring in several clinical studies.
- Experimental Drugs accountability.
- Relationships with various departments(Radiology, Pharmacy, pathological anatomy etc) of the hospital , Ethics Committee, pharmaceutical companies
- CRF design, submissions, budget planning
- Periodic reports of clinical studies
- Training GCP on February 2016

Business or sector *Hospital*



• **12/2016 → 04/2018**

Coordinator Research Unit Head&Neck

Istituto Nazionale dei Tumori, Milan

- Coordination and Data management of experimental Phase I/II/III Clinical Studies profit and no-profit in Oncology in compliance with protocol, SOPs, GCPs.
- CRFs
- Participation and supporting in monitoring visits, pre-study and close-out visits.
- Monitoring in several clinical studies.
- Experimental Drugs accountability.
- Relationships with various departments(Radiology, Pharmacy, pathological anatomy etc) of the hospital , Ethics Committee, pharmaceutical companies
- CRF design, submissions, budget planning
- Periodic reports of clinical studies
- Staff studies Phase I in accordance to determines AIFA
- Project manager in the several studies no profit
- Training GCP on February 2016

Business or sector Hospital

• **01/2011 → 11/2016**

Clinical Data Manager/ Senior Study Coordinator

ASST Grande Ospedale Metropolitano Niguarda, Milan

- Coordination and Data management of experimental Phase I/II/III Clinical Studies in Oncology in compliance with protocol, SOPs, GCPs.
- CRFs
- Participation in monitoring visits .
- Experimental Drugs accounting.
- Relationships with various departments(Radiology, Pharmacy, pathological anatomy etc) of the hospital , Ethics Committee, pharmaceutical companies
- CRF design, submissions, budget planning
- Periodic reports of clinical studies
- Staff studies Phase I in accordance to determines AIFA
- Training GCP February 2016 November

Business or sector Hospital

• **07/2010 → 12/2010**

Clinical Data Manager Internship

Ospedale Niguarda Ca' Granda -Milan

- Data Manager of many controlled Clinical Studies in GCPs.

Business or sector Hospital

• **10/2008 → 09/2009**

Internship

Molecular Pathology Laboratory at Health Center at Università degli Studi della Calabria – Arcavacata (CS)

Business or sector University



• 10/2006 → 04/2007

Internship

Farmacia Santoro – Via Caloprese, 48 – Cosenza (CS)

Gestione magazzino.

Business or sector Pharmacy.

EDUCATION AND TRAINING

• 01-2013 → 11.2013

Master's Degree in "Preclinical and Clinical Drug Development: technical-scientific, regulatory and ethical aspects"

Università Cattolica del Sacro Cuore – Rome (RM)

• 01-2010 → 01-2011

Master's Degree in "Oncological Pharmacy and Pharmacology"

Faculty of Pharmacy- Università degli Studi di Milano – Milan (MI)

• 2002 → 2009

Degree in "Pharmaceutical Chemistry and Technology" – vote 110/110 cum laude

Faculty of Pharmacy - Università degli Studi della Calabria – Arcavacata (CS)

• 1997 → 2002

Scientific High School Degree- vote 110/110 cum laude

High School G.B. Scorza – Cosenza (CS)

PERSONAL SKILLS

Mother Tongue

Italian

Other languages

English

French

UNDERSTANDING		SPEAKING		WRITING
Listening	Reading	Spoken interaction	Spoken production	
B2	B2	B2	B2	B2
C1	C1	C1	C1	B2

Communication skills	Excellent ability to team work and relationship with others, matured in situations where it was needed assistance of several figures and sharing the same equipment and environments.
Organisational / managerial skills	Excellent capability to take onerous commitments that require a strong sense of responsibility and initiative. Ability to work in stressful situations and organize the completion of the project on time, by daily programs. Flexibility and Enthusiasm.
Computer skills	Good Knowledge and use of: Oracle Clinical Software, Microsoft Office, Internet Explorer, Outlook Express.
Driving License	B

ADDITIONAL INFORMATION

Publications Presentations Projects Conferences Seminars Honours and awards Memberships References

- Investigators' meeting: "A randomized, multicenter, open-label phase II study of RO5083945 in combination with FOLFIRI versus FOLFIRI plus cetuximab or FOLFIRI alone as second line treatment in patients with KRAS wild-type or mutant metastatic colorectal cancer".
- Investigators' meeting: "A multi-center, open-label clinical trial to evaluate the objective response rate of bevacizumab in combination with modified FOLFOX-6 followed by one year of maintenance with bevacizumab alone in patients with initially not or borderline resectable colorectal liver metastases".
- Investigators' meeting: "A Randomised Open-Label Phase IIa Study to Assess the Efficacy and Safety of AZD4547 Monotherapy versus Paclitaxel in Patients with Advanced Gastric or Gastro-oesophageal Junction Cancer with FGFR2 Polysomy or Gene Amplification".
- Investigators' meeting: "A Randomized Phase III Study of Weekly ABI-007 Plus Gemcitabine Versus Gemcitabine Alone in Patients With Metastatic Adenocarcinoma of the Pancreas".
- Investigators' meeting: "A phase Ib/II, multicenter, open-label, dose escalation of LGX818 in combination with MEK162 in adult patients with BRAF V600-dependent advanced solid tumors".
- Investigators' meeting: "Open-label, Randomized, Controlled, Multicenter Phase II Trial Investigating 2 Sym 004 Doses Versus Investigator's Choice (Best Supportive Care, Capecitabine, 5-FU) in Subject with Metastatic Colorectal Cancer and Acquired Resistance to Anti-EGFR Monoclonal Antibodies".
- Investigators' meeting: "A PHASE 3, MULTICENTER, OPEN-LABEL, RANDOMIZED STUDY OF *nab*®-PACLITAXEL PLUS GEMCITABINE VERSUS GEMCITABINE ALONE AS ADJUVANT THERAPY IN SUBJECTS WITH SURGICALLY RESECTED PANCREATIC ADENOCARCINOMA.
- Participation in the training event "Job Advisor in Data Management" at Ospedale Niguarda Cà Granda and organized by Oncological Department from 20/03/2012 to 29/03/2012.
- Participation in FDA investigation at Ospedale Niguarda Falck Oncology about Bayer Clinical Study from 09/07/2012 to 13/07/2012.
- Participation in the following course at Ospedale Niguarda Cà Granda on 27/09/2012: "Validity of informed consent and applicability in critical situations. State of the art about regulatory aspects and challenges for the future".
- Participation in AIFA inspection at Ospedale Niguarda Falck Oncology about AstraZeneca Clinical Study from 29/01/2013 to 01/02/2013.
- Participation in SSFA seminar: "New Horizons in Clinical research" on 27/06/2013 at SSFA in Milan.
- Participation in the seminar "Carcinoma del colon-retto. Risultati raggiunti e prospettive di nuove cure" at Ospedale Niguarda Cà Granda on 12/09/2014.

- Participation in the training course "Preparation Course for the adaptation of centers of Phase I the mandatory requirements to run trials Phase I defined determines the AIFA of 19 June 2015" held by the Foundation Onlus Research and Health in Rome on December 14, 2015.
- Participation in the seminar "Carcinoma del colon-retto. ASST Grande Ospedale Metropolitano Niguarda Cà Granda on 22/11/2016.
- GIDM member.
- Collegial Discussion about clinical cases and problems in medical oncology practice.
- Participation in Tuesday's seminars held periodically at the Oncology Falck the Niguarda Ca 'Granda.
- Planning to Investigator Meeting for the study: " **HEALTH AND ECONOMIC OUTCOMES OF TWO DIFFERENT FOLLOW UP STRATEGIES IN EFFECTIVELY CURED ADVANCED HEAD AND NECK CANCER**"
- Planning and speaker for the Investigator Meeting for the study: **La personalizzazione della scelta terapeutica nei pazienti anziani con carcinoma localmente avanzato del distretto testa-collo -Definizione multidisciplinare della griglia di trattamento-**
- Participation in Tuesday's seminars held periodically at the Oncology Falck the Niguarda Ca 'Granda.
- Several staff training meetings in several staff training meetings Head&Neck.

I hereby authorise the use of my personal details (D.Lgs 196/03)

Milano, FIRMA