PERSONAL INFORMATION

Sara Manzella

Via Beniamino Donzelli 9, Montevecchia (LC), 23874, Italy

039-9930060

sara.manzella@comune.montevecchia.lc.it

Sex Female | Date of birth 30/01/1976 | Nationality Italian

WORK EXPERIENCE

from April 2016 to today

Franchisee - Consultant

Nutrition Consultant and Store Manager at Naturhouse (activity holder – self employed)

Preparation of a personal plan to achieve clients aims, based on physical analysis (weight measures and bioimpedence) and current eating habits. The method is based on the selection and proper combination of meals based on individual characteristics of each person and changing of habits, timetable etc., so that customer physiological, biochemical and metabolic needs are fully covered. The diet plan is supplemented by the patented and proved natural products composed of plant extracts. Reducing of weight is carefully monitored each week during planned visits and the changes in eating habits are reviewed, in order to achieve the "Healthy Weight".
Sales of herbal supplements.
Store management. From September 2018 to September 2019 one day a week nutritional consultant at NATURHOUSE Monza.

from February 2013 – to December 2015

Clinical Team Manager

PPD, Pharmaceutical Product Development

Responsible for the co-ordination and management of all Clinical Management project team members on an international basis (particularly CRA's), within designated projects. Implements and manages the necessary training, tracking and quality systems within the clinical portion of the project. Involved in regular and proactive liaison with the Project Manager, Clinical Managers and other functional groups as appropriate. Serves as the primary Clinical Management contact for the Project Manager. Co-ordinates standardised start up and clinical monitoring guidelines (in conjunction with query guidelines). Ensures essential document quality. Reviews monitoring visit reports. Performs co-monitoring visits where necessary. Identifies and performs any required troubleshooting activities. Manages query resolution process.
Studies followed as CTM:

- international Registry study, multi-centre observational survey, involving more than 2000 patients affected by Fabry disease. Management of pre-study evaluation visits for two additional countries, ad hoc transition visits from the former CRO, interim monitoring visits and site management calls; responsible for CRA training, including slide preparation. Managing a team of 14 CRAs in 12 countries, including 1 Lead CRA.
- phase III study on Medullary and Iodine-131 Refractory, Unresectable Differentiated Thyroid Cancer. Managed several cut-offs for the incoming primary analysis (DB lock for the primary analysis has been reached), in charge of Site Improvement Plan set up for sites at risk, involved in several activities in preparation of FDA inspection to 6 EMEA sites (including co-monitoring and inspection preparation visits) IP marketing authorisation received by FDA, EMA and Japan RA following successful completion of these inspections. Managing a team of 8 CRAs in 5 countries, including 2 LCRAs.
- phase III/IV study in patients with metastatic Medullary Thyroid Cancer. Management of site selection, pre-study evaluation visits and preparation of documents for EC submissions.
- open label Epilepsy extension study in the close-out phase; provided support for revision of COV reports and relevant addenda and final payment reconciliation.

As Unblinded CTM the two below studies in parallel:

- phase II, multi-centre study in patients with stage IIIB or IV Non-Squamous Non−Small Cell Lung Cancer (NSCLC) in maintenance phase; responsible for IP supplies and Temperature excursions management, and MVR review. Managing the transition from the unblinded to the blinded team in view of study closure. Managing a team of 7 un-blinded CRAs in 7 countries.
- phase II, multi-centre study in patients with stage IIIB Non−Small Cell Lung Cancer or Stage IV Squamous Non−Small Cell Lung Cancer (NSCLC) in maintenance phase; responsible for IP supplies/T excursions management, and MVR review; responsible for IP supplies and Temperature excursions management, and MVR review. Managing a team of 7 un-blinded CRAs in 7 Countries.

from October 2007 - to January 2013

Senior Clinical Research Associate

PPD, Pharmaceutical Product Development

Studies followed as senior CRA, with list of activities and responsibilities:

- phase II study of Metastatic Colon-Rectal Cancer. Supported start-up unit during site activations. Performed site initiation visits and interim monitoring visits, IEC amendment submission. Participated in one interim database lock. Used PPD CTMS and electronic CRF. As *Lead CRA* performed the following activities: management and follow-up of site issues, file reviews and samples trackers to be distributed to the team, reviewed annotated reports, PPD CTMS conventions and document packages, reviewed monitoring visit reports and acted as back-up for CTM when required.
- late stage study for patients with Bilateral Cataract (multi-focal IOL implantation compared to mono-focal IOL implantation). Performed interim monitoring visits and amendment submissions. Participated in final database lock. Used PPD CTMS and Query Direct.
- phase II study of Medullary and Iodine-131 Refractory, Unresectable Differentiated Thyroid Cancer. Supported start-up unit during the contract negotiation through to the review of the contracts. Attended CRA and Investigator Meetings. Performed site initiation visits and interim monitoring visits. Managed the safety database cut off. Used PPD CTMS.
- Performed feasibility activities for the following studies: Atopic Keratoconjunctivitis (AKC), blinded; Type II Diabetes Mellitus, blinded; Phase III adults with early IPF (Idiopathic Pulmonary Fibrosis), un-blinded; Non Infectious Uveitis, blinded. Performed feasibility activities and pre-study visits for a Chronic Obstructive Pulmonary Disease study and feasibility activities for two new phase III studies for Nausea.
- a global phase II/III study on Diabetic Macular Oedema. Performed interim monitoring visits, amendment of IEC submissions and managed the interim analysis and sponsor transition notification. Following new amendment IEC submission, managed second interim analysis and continuation to the 3rd year open-label phase, attended CRA meeting. As *Lead CRA*, performed the following activities: Acted as back-up for the CTM during short periods of time, performed protocol and eCRF training given to two new CTMs and CRAs, reviewed monitoring visit reports. Used PPD CTMS and client specific CTMS system.
- a global phase III study on Severe Sepsis. Performed initiation, close-out visits and motivational visits, amendment IEC submissions, attended CRA meeting and performed monitoring visits, participated to two data listing reviews, attended Sub-Investigator meetings, communicated Italian site closure to Regulatory Authority/IECs and performed final file review.

Other activities covered: accompanied field visits.

from June 2005 - to September 2007

Clinical Research Associate

PPD, Pharmaceutical Product Development

Studies followed as CRA, with list of activities and responsibilities:

- Performed feasibility activities for a Synovial Cell Sarcoma, Chondrosarcoma, Diabetic Macular Oedema (DME) and patients with Retinal Vein Occlusion patients (BRVO & CRVO) studies.
- global phase III study on Age Related Macular Degeneration. Performed initiation and interim monitoring visits. Attended CRA meetings. Performed Lead CRA activities.
- global phase II study on Age Related Macular Degeneration. Performed interim monitoring visits and close-out visit.
- global phase III study on Age Related Macular Degeneration. Performed interim monitoring visits.
- global phase IIIb study on patients with congenital disorders of red blood cells and chronic iron overload from blood transfusions. Performed amendment submission to IECs and pre-study visits on site and by phone.

from January 2005 - to May 2005

Research Assistant

PPD, Pharmaceutical Product Development

Studies followed as RA, with list of activities and responsibilities:

- global phase III study on Lupus Nephritis. Performed EC submissions and accompanied CRA on pre-study visits.
- global phase III early access programme study in HIV. Reviewed Country and Investigator files, supported CRAs to schedule close-out calls and performed administration activities at site.
- global phase III on Age Related Macular Degeneration. Performed EC submissions and accompanied CRA on monitoring visits.

from November 2003 - to January 2005

Research Assistant

OPIS, Desio, Italy

Research Assistant as part of start-up unit for various studies. Performed submissions and finalised contracts with sites. Studies were related to various therapeutic areas (cardiovascular, oncology and respiratory in particular).

from January 2002 to October 2003

Scientific Informer

VALEAS S.p.A. (Pharmaceutical Industry), Milan, Italy

Worked in the marketing area to promote various pharmaceuticals products, in particular related to the respiratory area.

EDUCATION AND TRAINING

from 1995 – to 2001

Bachelor's Degree Biology, 2001

University of Milan, Milan, Italy
Grade: 110 cum laude

from 1991 – to 1995

High school diploma, 1995

Liceo Scientifico G.B. Grassi, Lecco, Italy
Grade: 56/60

LICENSES and CERTIFICATION

Trained in ICH-GCP and applicable SOPs, at OPIS (C.R.O.), Desio, Italy
Completed PPD Clinical Foundation Programme, August 2005 + all PPD trainings required to be completed on a monthly basis + several Project Specific trainings upon request
CRA qualified to perform monitoring activities independently according to the Italian regulations
CTM trainings

Naturhouse trainings:
- biochemitry and nutrition;
- supplemental foods and plants extracts;

21° corso ECM di Alimentazione e Nutrizione Umana at Scuola Nutrizione Salernitana in 2020 (human nutrition)

PERSONAL SKILLS

Mother tongue(s): ITALIAN

Other language(s)

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

Use of English on a daily basis since 2005 both oral and written (emails, conference calls with international team, internal course attended in 2014); Shenker course attended in 2008; British Institute course attended in 2004

Communication skills: good communication skills gained through my experience as clinical team manager and lead CRA in international team

Organisational: good organisational skills gained through working experience. I worked both as office and home based support employee

Job-related skills - Other skills: Very good capabilities of working in team – strong attitude in building good relationship
Sales representative certificate year 2002

Computer skills: good command of Microsoft Office™ tools; use of Clinical Trial Management System at PPD, use of electronic CRF, use of different IVRS system; use of electronic filing system.

Driving licence: B

ADDITIONAL INFORMATION

Volunteer with disable people – volunteer reader for children in library
courses attended at "Scuola Agraria del Parco di Monza" about herbal medicines and gardens
Personal hobbies: cinema, books, theatre, pilates&yoga