PERSONAL DATA

Name: Margherita Barbieri

EDUCATION

2008 Specialist In Group and individual psychanalytical Psychotherapy at C.O.I.R.A.G. and AS. VE. GR.A

2002 Major psychology – University of Padua– Faculty of Psychology

2001 Obstetric Psycho-prophylaxis course

1995: high schools: classical high school at Liceo Classico

PRESENT POSITION 04 November 2019

Clinical Study Coordinator at Rheumatology ward: "UOC Reumatologia of IRCCS Policlinico San Matteo – Pavia"

Responsibilities include:

The study coordinator is responsible for the following activities:

Assists the site staff with study set-up activities.

Serves as primary project contact with CRO; CRAs and Sponsors to ensure appropriate communication channels are maintained and reporting schedules adhered to.

Serves as a project management liaison with other groups within the Trial

Supports all Local regulatory activities necessary to start and conduct the clinical trial at the investigational site,

Assists site staff and study physicians in development of patient's enrolment strategies

Supports Medical team in carry on clinical trials in compliance with Protocols, applicable local regulation, GCPs, guidelines and SOPs.

Supports all the site staff in arrange, manage and follow up protocol related visits scheduling for each involved subject

Assists with project specific administrative activities as a member of the project team.

Takes care of the distribution of the information (i.e. SAE, protocol amendments, etc) among the different subjects of the study (Sponsor, Investigators, Clinical Research Associate) and is also responsible for the study product storage resupply distribution accountability and tracking. (IMP, NIMP, KITs study material)

Attends to regular face to face meetings with the Sponsor's representatives and support CRAs in on site pre study, Initiation, monitoring and close out visits

Maintains Investigator study files up to date and complete.

Ensures that all the CRFs will be filled in correctly, accurately and in a timely manner

Ensures correct queries resolution in accordance with specific study timelines.

PREVIOUS POSITIONS

17 January 2017- 10 September 2019 – Clinical Trial Assistant and Training expert

Responsibilities include:

Supports Clinical Operations Managers with overseeing operational activities related to planning, executing, and reporting of Phase 3 and 4 clinical trials;

Ensures the correct filing and quality control of study documents in accordance with SOPs, ICH/GCP guidelines and local regulations; Actively contributes to results oriented department goals; Drives continuous improvement of formative International Projects;

Contributes to the local customization of the draft informed consent template, ensuring Local contact is added; Assist the Clinical Operation Manager in the conduct of regulatory process for new clinical protocols if required;

Contributes to the contact and follow up of clinical investigators involved in the CIRM Projects and clinical trials.; Work with the Clinical Operations Managers and Senior Associate Clinical Operations Management colleagues to perform follow up for studies issues and deadlines.

Coordinates and support all the activities related to related with the process of instruction of foreign clinical centers for the adaptation to a high quality standard, relative to the rules of good practice in clinical standards.

June 2015 – December 2016 -Freelancer for clinical trials Set -up and start Up Activities:

Responsibilities include identification, contact and follow up with the purposed Pricipal Investigators.
Collect review and archive initial sets of study documents in accordance with promoter/ sponsor SOPs/WPs, applicable regulations and the principles of ICH-GCP Involvement,
Contacts possibly involved ECs to find out lists of local documents and template, Local ECs rules and meeting calendar.
Reviews and adapt Master document (mainly from English to Italian) for local requirements.
Prepares submission packages

May 2009– June 2015 - Psychological Assistance

role of Educator and psycho-educational assistant for adults and minors with different psychological problems.
the activities concerned both home assistance and institutions such as social services (ASL, SerT, schools, ect).

June 2008 – April 2009 – Psychologist "Comunità San Gaetano Vicenza"

psychology activities for both individual and group psychotherapy to support drug-addicted patients. Responsibilities included the management of drug-addicted patients from access and through all the detoxification and recovery steps up to reintegration into a normal life conduct.

From January 2006 until now

private therapeutic activity for counseling, diagnosis and psychotherapeutic treatment in dual and group settings (homogeneous groups at term. Activity conducted in private practice)

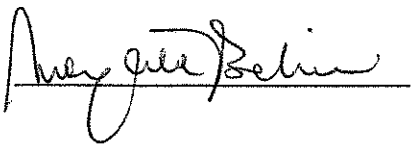
SKILLS

Good Knowledge of computer skills and experience in the use of standard office programs (Word, Excel, Power Point etc.).
Good interpersonal skills,
Team working and problem-solving attitude

Good English written and spoken
ICG – GCP Certification valid until 11 march 2022
IATA training performed on March 2019

I agree to the use of my personal data accordingly to the GDPR 679/2016 and to "D. lgs. N° 196, 30 giugno 2003"

Margherita Barbieri



Date:

27-01-2021