Curriculum Vitae

Over 14 years' experience in in the conduct and oversight of clinical trials spanning all phases, both in Pharma Companies and in Clinical Research Organizations. Began her carrier as CRA and grew to Manager of Clinical Operations role. Deep clinical operations knowledge and clinical monitoring background. High focus on proactive quality management. Strong communication, organizational and problem resolution skills. Seeks to continuously improve workplace output in an effort to meet and exceed operational objectives and requirements.

Work History

Title: Manager of Clinical Operations
Company/Location: ICON, formerly PRA Health Sciences, Milan, ITALY
Dates: Sep 2019 - Present
Responsibilities:

- Develops plans to support growth and career development of assigned Clinical Operations employees as well as manage the delivery of quality performance
- Responsible for selecting, training, and developing a team comprised of CRAs
- Responsible for supporting daily activities of the team members in order to ensure all projects are completed on time, in budget, and in compliance with all standards
- Ensures staff development and performance feedback are provided through activities such as mentorship and career development
- Responsible for the management of resources and resource projections to ensure project teams are consistent with client needs and expectations
- Promotes a positive and professional work environment that attracts and retains the best talent and delivers services that exceed customer expectations
- Point of escalation for resolution of issues and conflicts

Title: Senior Clinical Research Associate
Company/Location: ICON, formerly PRA Health Sciences, Milan, ITALY
Dates: Jul 2012 - Sep 2019
Responsibilities:

- Conducts site selection, initiation, monitoring, and close-out visits for research sites according to the monitoring plan, and sponsor SOPs, ICH GCP guidelines and applicable regulations
- Performs source data verification and assists sites with query resolution and followed up on outstanding queries
- Prepares site visit reports and follow-up letters to the investigators
- Built productive relationships with investigators and site staff to achieve study objectives, including patient recruitment targets
- Performs source data and patient's records verification, ensures on-site study drug storage, dispensing, and accountability, data collection, and regulatory document collection is adequate
- Reports safety concerns, protocol deviations, and/or unexpected data trends
- Primary contact for study site personnel
- Provides training to site personnel
- Participated in team meetings
- Performs essential document site file reconciliation
- Responsible for clinical study documentation collection by ensuring compliance with applicable local regulations and ICH guidelines
- Maintains paper and electronic Trial Master File
- Interacts to project teams in order to ensure that regulatory standards and working relationships are maintained

Curriculum Vitae

Title: Senior Clinical Research Associate
Company/Location: I.P.A.S. SA, Ligornetto, Ticino, SWITZERLAND
Dates: Jan 2009 - Jun 2012
Responsibilities:

- Leads CRA mentoring and supervising other CRAs
- Performs regulatory submission and updates to CA/EC (Italian and Swiss regulations)
- Performs pre-study, initiation, monitoring and close-out visits
- Ensures Adverse Events are reported appropriately, accurately and in a timely manner and that follow-up activities are conducted as necessary
- Ensures complete and thorough study drug reconciliation
- Maintains source documents and regulatory documentation of clinical trial
- Creates Standard Operating Procedures for each clinical trial
- Provides study status updates to team members and project management, including interaction to resolve site issues and facilitate project timelines
- Provides support and timely follow-up for all audit and quality assurance activities

Title: Clinical Research Associate
Company/Location: Philogen, Siena, SI, ITALY
Dates: Feb 2008 - Nov 2008
Responsibilities

- Performs regulatory submission to CA/EC
- Conducts monitoring visits to confirm protocol compliance, assess qualifications of study personnel, ensure “Good Clinical Practice”, and conduct close-out visits
- Verifies data in source documents are in agreement with source, initiate data query resolution and confirm resolution in timely manner
- Performs investigative site file reconciliation: requests any new and updated site-related essential documents and reviews them for content, consistency with other documents, and compliance with appropriate local regulatory requirements, ICH guidelines, SOPs, and sponsor requirements
- Assists with the preparation of IRB applications, including protocol and informed consents and obtains approval to conduct the study
- Maintains appropriate correspondence with the IRB, including adverse events, annual renewals and protocol amendments

Title: Clinical Research Associate
Company/Location: Medical Trial analysis M.T.A., Ferrara, ITALY
Dates: Apr 2007 - Dec 2007
Responsibilities:

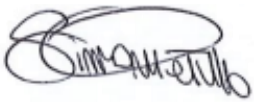
- Performed regulatory submission to CA/EC
- Works under supervision to manage work flow to accomplish assigned objectives
- Assists in investigator study site selection and study start-up
- Performed on-site monitoring visits evaluating protocol and regulatory compliance, including source document verification, informed consent process, data integrity, and drug accountability compliance
- Collects and reviews site regulatory documents for accuracy and completion
- Provides study training and guidance to designated site personnel

Language

Language	Conversational	Reading	Writing	Medical Records /Terminology
English	High	High	High	High
Italian	High	High	High	High

Education

- **High School, Scientific Diploma, Jun 2000**
  Liceo Scientifico “Leonardo da Vinci", Calitri (AV), ITALY
- **Graduate, Chemistry and Pharmaceutical Technologies, Oct 2006**
  Università degli Studi di Ferrara, Ferrara, ITALY
- **Graduate, Master Degree in Epidemiology and Clinical Trial School, Oct 2007**
  Università degli Studi di Ferrara, Ferrara, ITALY



Signed by: PetulloSimona
Clinical Operations Manager
Reason: I attest to the accuracy and integrity of this document.
Date & Time: 09 Dec 2021 03:46 PM +01:00

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