**TRUONG Quynh Nhu**

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# **Summary of Qualifications & Experience**

I have a total of 12 years of experience in the clinical research industry. This includes 11 years of experience as a clinical research associate (CRA), 1 year as a local project manager (L-PM) and primary CRA.

Working in Clinical Trials, I have worked across the full scope of activities in global research, from study start-up (feasibility), site initiation, monitoring, study closure, audit activity, inspection activity. I have experience covering a wide therapeutic area including gastroenterology, hepatology, urology, cardiology, oncology, psychiatry, vaccines.

Before that, I had 4 years of experience in the arena of regulatory affairs. During this time, I prepared and translated all the necessary documents. I am the person in charge of the final translated documents that are officially exploited for submission to the regulatory authority.

Being a CRA, besides reviewing and finalizing translated documents of my clinical projects which are delivered by translation vendor, I often work as a freelance translator for medical/clinical documents in my spare time. I understand the non-creative linguistic styles used for the protocol and in a slightly simpler, less complicated way for the informed consent form to be addressed to the patients.

When translating medical/clinical documents, I always adhere to the scientific context, and at the same time consider the contemporary Vietnamese language, and ensuring a fluent and coherent style.

Therefore, I have about 16 years of experience in translating, editing, and reviewing medical/clinical documents.

I can translate documents including but not limited to the list below:

- Protocol, informed consent form, investigator brochure, patient diaries, questionnaires. SAE report, SUSAR report, correspondences, study progress report.

- Summary of product characteristic, instructions for use, packaging labels, brochures, slide sets, medical care plans.

Vietnamese is my native language, I am fluent in English and experienced in the fields of general medicine, pharmaceuticals, clinical research. I have a good knowledge of medical/clinical literature. I have a passion for reading and working with medical documents. I also have experience working with CAT tools e.g., Trados, Wordfast, MemoQ.

I am confident that I am a good translator for medical and clinical documents. With my knowledge and experience, I believe that my work is highly productive, high quality and requires little checking and correcting.

**Education**

Master Degree (Pharmaceutical & clinical development)- University of Poitiers, France-30 Oct 2008

Bachelor-Pharmacist-Medicine and pharmacy university of Ho Chi Minh city, Viet Nam-04 Oct 2002

**Country Experience**

Vietnam

**Languages**

Vietnamese (Native)

English (Good/ Proficient)

French: Read, speak, and write in middle level

**Contact details**

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# **Employment history**

**Jan 2023 to Apr 2023** Senior Clinical Research Associate-IQVIA RDS Vietnam

**Therapeutic Areas**: Pulmonary arterial hypertension (PAH)

* Participates in the investigator recruitment process.
* Coordinates activities with the site in preparation for the initiation of the study.
* Obtains regulatory documentation for successful implementation, monitoring, and evaluation of clinical trials.
* Works with site staff to obtain regulatory (IRB/IEC) approval of study specific documents.
* Performs study initiation activities, reviewing with the site personnel the protocol, regulatory issues, study procedures, and provides training on completion of the eCRF; monitoring activities and study close-out activities.
* Trains site staff on the EDC system, and all other study related electronic systems and verifies site computer system.
* Assists in resolving any issues to ensure compliance with protocol, GCP and regulation.
* Assures adherence to Good Clinical Practices, investigator integrity, and compliance with all study procedures through on-site monitoring visits. Performs validation of source documentation as required by sponsor. Prepares monitoring reports and letters per the timelines defined in IQVIA and or sponsor SOPs.
* Documents accountability, stability and storage conditions of clinical trial materials as required by sponsor.  Performs investigational product inventory.  Ensures return of unused materials to designated location or verifies destruction as required.
* Reviews the quality and integrity of the clinical data through in house review of electronic CRF data and on-site source verification. Works with sites to resolve data queries.
* Serves as primary contact between IQVIA and investigator; coordinates all correspondence; ensures timely transmission of clinical data with the study site and technical reporting, as requested.
* Performs study close-out visits per the study specific Clinical Monitoring Plan including final investigational product reconciliation and disposition, site study file reconciliation, data query resolution through to database lock and resolution of outstanding action items.
* Assists with, and attends, Investigator Meetings for assigned studies.
* Authorized to request site audits due to data integrity concerns.
* Attends study-related, company, departmental, and external meetings, as required.
* Ensures internal and study-related trainings are completed per IQVIA and/or study timelines.
* Ensures all study deliverables are completed per IQVIA and study timelines.
* Performs other duties, as requested.

**Sep 2021 to Nov 2022** Clinical Research Associate, local project manager, primary CRA -Vietstar Biomedical Research, Vietnam

**Therapeutic Areas**: IgA nephropathy, COVID19 Vaccine, COVID19 treatment

* Performs site qualification, site initiation, interim monitoring, site management activities and closeout visits (performed on-site or remotely) ensuring regulatory, ICH-GCP and/or Good Pharmacoepidemiology Practice (GPP) and protocol compliance. Uses judgment and experience to evaluate overall performance of site and site staff and to provide recommendations regarding site-specific actions; immediately communicates/escalates serious issues to the project team and develops action plans. Maintains a working knowledge of ICH/GCP Guidelines or other applicable guidance, relevant regulations, and company SOPs/processes.
* Conducts Source Document Review of appropriate site source documents and medical records.
* Verifies required clinical data entered in the case report form (CRF) is accurate and complete.
* Applies query resolution techniques remotely and on site, and provides guidance to site staff as necessary, driving query resolution to closure within agreed timelines.
* Site support throughout the study lifecycle from site identification through close-out.
* Training new staff, study site staff.
* Presenting slide set at initiation visits.

**Dec 2020 to Aug 2021** English <-> Vietnamese freelance translator for medical/clinical document

**Feb 2011 to Sep 2020** Clinical Research Associate II - EPS International Vietnam Ltd, Vietnam **Therapeutic Areas**: Oncology, Psychiatry, Cardiovascular

**Responsibilities:**

* Set up an investigator site in a timely manner
	+ Appropriate investigator site set-up and implementation including set up and update the trial and site information in Clinical Trial Management System or equivalent trackers and other study management system in a timely manner including in house administration activities.
* Site Management
	+ Deliver good quality data in a timely manner.
	+ Protect patient’s rights and safety.
	+ IP management.
* Close investigator sites
	+ Appropriate investigator site close-out and implementation.
* Build up the relationship with key partners
* Perform site feasibility, country feasibility and protocol feasibility
* Support to build up a study team
* Office management, BD support
* Clinical trial management system

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| **Feb 2010 to Jan 2011** Clinical Research Associate - GlaxoSmithKline, Vietnam representative office, Ho Chi Min city. Vietnam  |

**Urology-Prostatitis -Phase III**

* Work in close collaboration with study team in order to complete study protocol, plan study budget, develop contracts for study, make available for all study related documents, templates, forms, import the study supply (study medication), develop Study monitoring plan, develop Case report form in paper.

**Gastroenterology-Hepatitis B-phase IV**

* Co-monitor, working with outsource Contract research organism (CRO).
* Follow up the monitoring activities carried out by the outsource CRO.
* Check and synthesize monitoring visit reports received from CRO.
* Follow up study progress.
* Perform co-monitoring visits with CRAs of CRO.
* Handle payment management to investigators and outsource CRO.
* Organize the investigator meetings.

**Nov 2004 to Jul 2007** Regulatory affairs manager-Medco company, Ho Chi Minh city, Vietnam

* Direct contact with the clients that are pharmaceutical companies from Pakistan, India, Indonesia, Italy, and Germany.
* Complete registration dossiers for medicine, vaccine, cosmetic, food supplement.
* Keep in contact with the collaborators at Hanoi and the regulatory authorities at Ministry of Health to follow up the status of the registration dossiers.
* Explain and resolve all emerged problems during the process such as supplementary dossiers, validation of drug specification according to the requests of Ministry of Health to be able to get the Visa number.
* Follow up the circulation term of products, plan for the in time re-registration, ensure the uninterrupted circulation.

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| **Mar 2003 to Oct 2004** Regulatory affairs executive- Korea pharmaceutical company Shinpoong, Ho Chi Minh city, Vietnam |

* Take part in the editing registration dossiers for under license produced medicines of the company.
* Take part in the supplementation of the registration dossier.
* Train the new employees in product information.
* Prepare the pharmaceutically specific documents for seminaries to present company products to clients.
* Present products to clients at seminaries.

**Nov 2002 to Feb 2003** Medical representative-Pharmaceutical company Meyer, Vietnam

* Meet and present company products to the clients, be in charge of hospital field.
* Keep in contact with the client to get the orders.

**Clinical trial experience:**

* **Study phase: Phase III**

 Indication: Medication of Pulmonary arterial hypertension

 Sponsor: International Sponsor

 Role: Senior Clinical Research Associate

Number of subject: 15-30

Activities involved:

Local EC/National EC submission

Site management

Site Interim monitoring visit

* **Study phase: Phase III**

 Indication: Medication of IgA nephropathy

 Sponsor: International Sponsor

 Role: Clinical Research Associate

Number of subject: 3-5

Activities involved:

Site set up

Local EC/National EC submission

Site management

* **Study phase: Phase III**

 Indication: Medication of Covid19 disease

 Sponsor: International Sponsor

 Role: Clinical Research Associate

Number of subject: 705

Activities involved:

Site Interim monitoring visit

Site management

* **Study phase: Phase III**

 Indication: Preventive vaccine of Covid19 disease

 Sponsor: International Sponsor

 Role: Unblinded local project manager

Number of subject: 8835

Activities involved:

Site Interim monitoring visit

* **Study phase: Phase III**

 Indication: Preventive vaccine of Covid19 disease

 Sponsor: Domestic Sponsor

 Role: Clinical Research Associate

Number of subject: 2675

Activities involved:

Site Initiation visit

Site Interim monitoring visit

Site management

* **Study phase: Phase IV**

 Indication: Colorectal Cancer

 Sponsor: International Sponsor

 Role: Clinical Research Associate

Number of subject: 12

Activities involved:

Site Interim monitoring visit

Site management

Local EC/National EC submission

Site Closeout visit

* **Study phase: Phase III**

 Indication: Psychiatry

 Sponsor: International Sponsor

 Role: Clinical Research Associate

Number of subject: -

Activities involved:

Site feasibility

* **Study phase: Phase III**

 Indication: Hypertension

 Sponsor: International Sponsor

 Role: Clinical Research Associate

Number of subject: 43

Activities involved:

Investigator meeting

Site Initiation visit

Site Interim monitoring visit

Site management

Local EC/National EC submission

Site audit

* **Study phase: Phase III**

 Indication: Coronary artery disease

 Role: Clinical Research Associate

 Sponsor: International Sponsor

Number of subject: 100

Activities involved:

Site Initiation visit

Site Interim monitoring visit

Site management

Local EC/National EC submission

Site inspection

* **Study phase: Phase III**

 Indication: Prostatitis

 Role: Clinical Research Associate

 Sponsor: Domestic Sponsor

Number of subject: -

Activities involved:

Development of Clinical trial-related documents (paper CRF)

Site selection

* **Study phase: Phase IV**

 Indication: Hepatitis B

 Role: Clinical Research Associate

 Sponsor: Domestic Sponsor

Number of subject: 1000 Activities involved:

Project management

Site co-monitoring visits

**Training Courses:**

2023 Good Clinical Practice (Trainer: Vietnam Ministry of Health)

2021 Good Clinical Practice (Trainer: Vietnam Ministry of Health)

2020 ICH GCP E6 (R2) (Trainer: The MRCT of Brigham and women’s hospital and Harvard):

* What is ICH E6(R2) and how does it apply to regulators?
* 13 principles of ICH GCP
* IRB IEC responsibility
* Investigator quality & responsibility
* Sponsor responsibility
* Protocol & Investigator brochure
* Essential document
* GCP in practice for reviewers: risk-based monitoring, quality by design
* GCP in practice for Inspectors
* GCP summary