

# AQSA SOHAIL

CLINICAL STUDY COORDINATOR IN RADIOLOGIA E

INTERVENTISTICA & MEDICINA NUCLEARE | Milano, Italia

## SUMMARY

I am a clinical study coordinator working on Phase II, III, and IV clinical trials, with a strong focus on GCP compliance, data quality, and study coordination. I am skilled in supporting trial operations, documentation, and collaboration with multidisciplinary research teams.

## SKILLS & ABILITIES

Experienced in Phase II, III, and IV clinical trials, with solid expertise in trial coordination, regulatory compliance, and data management. I am proficient in ensuring adherence to Good Clinical Practice (GCP), supporting patient recruitment and follow-up, managing study documentation, and maintaining high-quality data across multicenter studies.

## EXPERIENCE

### **Clinical Study Coordinator Feb 2025—Current at Fondazione IRCCS Istituto Nazionale dei Tumori - Milano, Italia**

Coordination and operational management of Phase II–III Thyroid cancers in nuclear medicine and phase IV post-marketing studies in hepatocellular carcinoma (HCC) in radiology, including compassionate use protocols. Support in multidisciplinary team coordination (investigators, research nurses, pharmacists, laboratories, and institutional departments). Sponsor/CRO interface for monitoring, data management, and pharmacovigilance-related activities. Oversight and maintenance of the Investigator Site File, including protocol amendments, regulatory communications, and Ethics Committee submissions. Data management and eCRF handling (data entry, query resolution, and source verification) using systems such as Veeva Vault, Redcap, Calyx, I Medidata, Castor & Zelta. Management of IWRS/IVRS systems and randomization workflows. Planning and organization of monitoring visits. Pharmacovigilance activities: SAE reporting and coordination with the Safety Department within regulatory timelines. Anonymization of diagnostic and radiological images (DICOM format) with syngo plaza in compliance with GDPR and GCP standards for secure transfer to Sponsors/CROs. Knowledge of GCP, GDPR, and current regulations in clinical research.

### **Clinical Study Coordinator (Internship) at A.O.U Maggiore Della Carità —Novara, Italy Mar 2023—Oct 2024**

Supported clinical trial operations by assisting in patient recruitment, screening, and informed consent processes. Conducted data entry and verification, ensuring accurate and timely updates to clinical trial databases. Assisted with the preparation and organization of regulatory documents and trial materials. Maintained trial documentation, including patient records and study logs, ensuring compliance with regulatory requirements. Collaborated with clinical research teams to monitor trial progress and adherence to study protocols. Assisted in

coordinating communication between research staff, trial sites, and sponsors. Provided administrative support, including scheduling meetings, preparing reports, and tracking trial timelines.

**Teaching Assistant at Università del Piemonte Orientale -  
Novara, Italia Oct 2023—Dec Dec 2023**

Provided one-on-one or group tutoring sessions to students in the field of functional genomics. Assisted students in understanding complex concepts. Developed customized study plans and resources to facilitate student learning and comprehension.

**Pharmacist at Health Mart Servaid Pharmacy Pvt. Ltd., Dec  
2020—Oct 2021**

As a community pharmacist, I provided expert advice on medication use, ensuring patients understood their prescriptions, side effects, and drug interactions. Managed prescriptions, reviewed for accuracy and appropriateness, and delivered personalized medication therapy management to optimize patient outcomes. Collaborated with healthcare professionals to coordinate care, participated in health promotion initiatives, and administered clinical services like vaccinations. Additionally, I handled inventory management, ensuring regulatory compliance and maintaining accurate patient records, while offering exceptional customer service to resolve health-related inquiries.

**EDUCATION**

Università del Piemonte Orientale, Novara, Italy

2022—2024 | MSc in Medical Biotechnology

Lahore College For Women University, Lahore, Pakistan

2013—2019 | Doctor of Pharmacy (Pharm-D)

**TRAINING IN  
CLINICAL RESEARCH**

Sperimentazioni cliniche di Fase II & III, ICH Good Clinical Practice E6 (R2) – Global Health Network, Score 89% (22/11/2023),  
Management of Present and Future Clinical Trials – Istituto Nazionale dei Tumori, Milan (03/02/2025–28/02/2025) ICH Good Clinical Practice E6 (R3) – Global Health Network, Score 100% (29/07/2025)  
GCP E6 (R3) ,  
Update Meeting Istituto Nazionale dei Tumori, Milan (09/06/2025)  
Conduct of Phase I Clinical Trials —Istituto Nazionale dei Tumori, Milan (16/06/2025) GDPR (EU 2016/679) in Clinical Care and Research —Istituto Nazionale dei Tumori, Milan (2025)

**LANGUAGES**

I can speak English, Urdu, Punjabi, Hindi and Italian