

SUMMARY

Jieun has 2 year and 7 months experience in Clinical Research Associate with Dt&SanoMedics and Dt&CRO. Jieun has worked across a range of therapeutic areas including Hepatobiliary and Pancreatic Surgery, Dermatology, Burn Surgery and Oncology.

Before working as a CRA, Jieun worked as a Registered Nurse at Pediatric Intensive Care Unit, Diabetic Mellitus Education Center and Artificial Kidney Unit.

Jieun has good communication skill that makes her effectively interact with Study team members and site staffs. In addition, her adaptability, integrity, and persistence are one of the great advantages of working as a CRA.

SKILLS

- Phase II, III, IV, Medical Device study
- **Therapeutic areas:** Hepatobiliary and Pancreatic Surgery, Dermatology, Burn surgery, Oncology
- EDC Systems: CRScube, Medidata

Work Experience

Clinical Research Associate (Mar 2022 - Current)

Dt&SanoMedics, Dt&CRO - Seoul

- Communicate with PM, CRM, other CRAs, Sponsor and site staff as appropriate.
- Work in a timely manner in accordance with the agreed budget under the supervision of PM/LM.
- Ensure that all required documentation is in place and maintained during study.
- Prepare and submit IRB amendment and ensure that IRB is updated regarding protocol amendments, SAE, PD, etc
- **Conduct pre-study, study initiation, study monitoring, and study close-out visits.**
- Participate and support in audit and inspection.
- Collaborated with clinical study site and sponsor to troubleshoot and provide solutions to study-related issues.

Registered Nurse (Sep 2021 – Mar 2022)

K&C Medi-clinic - Seoul

- Perform Hemodialysis for patients with Chronic Kidney Disease.
- Administer medications via oral, IV, intramuscular, and subcutaneous injections and monitored responses.

Registered Nurse (Aug 2019 - May 2021)

Woorihyosarang Nursing Hospital – Seongnam-si, Gyeonggi-do

- Perform Hemodialysis for patients with Chronic Kidney Disease.
- Administer medications via oral, IV, intramuscular, and subcutaneous injections and monitored responses.

Education Nurse (May 2018 - Dec 2018)

Kangbuk Samsung Hospital – Seoul

- Educate patients with Diabetic Mellitus about measuring and controlling blood sugar level in daily life with smart phone application

Languages

- Korean - Native
- English – Intermediate
(Toeic, 905, 2022)

Education

- Degree - Bachelor
Hanyang University /
Seoul
Department of Nursing
Mar 2013 – Feb 2017

License

- Registered Nurse
377144, Korea

Registered Nurse (Nov 2017 - Mar 2018)

Samsung Medical Center – Seoul

- Perform Nursing duties in Pediatric Intensive Care Unit.
- Administer medications via oral, IV, intramuscular, and subcutaneous injections and monitored responses.
- Assess patient with ventilator treatment and evaluate respiratory function

Clinical Research Experience

Prostate Cancer, Phase 2, Local Study (Aug 2022 – Jun2024)

- On-site monitoring (SIV, SMV)
- Submission to the site IRB
- ISF and TMF Management
- SAE/SUSAR/PD Report
- Data monitoring / Query resolution

Prostate Cancer, Phase 3, Local Study (Feb 2023 – current)

- On-site monitoring (PSV, SIV, SMV) / CI site
- IRB Initial submission, Contract, Budget Planning
- Submission to the site IRB
- In-house, On-site Sponsor Audit
- ISF and TMF Management
- SAE/PD Report

Liver Transplantation, Phase 4, Local study (May 2022 – current)

- On-site monitoring (SIV, SMV)
- Submission to the site IRB
- ISF and TMF Management
- Budget Management, Contract Amendment
- SAE/PD Report
- Data monitoring / Query resolution

Second-degree Burn, Medical Device, Local study (May 2022 – Dec 2022)

- On-site monitoring (SMV, COV)
- Submission to site IRB
- ISF and TMF Management
- Data Cleansing / Query resolution

Temporary Restoration of Mid-face Volume, Medical Device, Local Study (Aug 2022 – Sep 2023)

- On-site monitoring (SIV, SMV, COV)
- Submission to the site IRB
- ISF and TMF Management
- ISO14155 Inspection, Site Audit
- Budget Management, Contract Amendment
- SAE/PD Report
- Data Cleansing / Query resolution

Nasolabial Fold, Medical Device, Local Study (Jan 2024 – current)

- On-site monitoring (SIV, SMV)
- Submission to the site IRB
- ISF and TMF Management
- Site Audit
- Budget Management, Contract Amendment

Temporary Restoration of Mid-face Volume, Medical Device, Local Study (Jan 2024 – current)

- On-site monitoring (SIV, SMV)
- Submission to the site IRB
- ISF and TMF Management
- ISO14155 Inspection, Site Audit
- PD Report