

Observational Research Specialist II

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Company: Parexel

Location: Poland

Category: life-physical-and-social-science

When our values align, there's no limit to what we can achieve.

We are currently looking for an Observational Research Specialist II to join the team in EMEA. You must be a fluent German speaker and be based in one of the following countries:

Croatia - Any Region - Home Based

Czech Republic - Any Region - Home Based

Poland - Any Region - Home Based

Hungary - Any Region - Home Based

Romania - Any Region - Home Based

Serbia - Any Region - Home Based

Netherlands - Any Region - Home Based

Belgium - Any Region - Home Based

Some travel to Germany will be required.

In this role you will independently provide site management and support activities for

Observational/ Non-interventional research study sites in accordance with relevant Standard Operating Procedures (SOPs), study-specific procedures and regulations. Responsible for supporting the development of the Clinical Operations service delivery within Parexel.

Key Accountabilities:

Depending on study assignment and with support as necessary key accountabilities can include:

Primary contact for assigned sites and build positive business relationships with physicians and site staff.

Site identification, selection and start-up activities including negotiation of site agreements and budgets.

Customization of country/site specific documentation.

Conduct of all remote and on-site monitoring activities through all study stages.

Identification of potential out of scope activities.

Perform regular reviews of data according to Site Management Plan (SMP).

Responsible for the completeness and quality of the site files for the assigned sites.

Maintain study management system(s) on a daily basis.

Maintain a working knowledge and ensure compliance with applicable Good Pharmacoepidemiology Practices (GPP) guidelines, local country requirements, SOPs and study specific procedures.

Contribution to department service delivery and participation in initiatives.

Knowledge and Experience :

Strong experience with Observational/ Non-interventional research studies.

Able to manage study from FEAS to Close out (including Ethics Committee submission and CSA negotiation)

Must be a fluent German speaker.

Education:

Degree in a life science, nursing qualification or other relevant experience required.

Skills:

Excellent interpersonal, verbal and written communication skills.

Thorough knowledge of Observational/ Non-interventional study research and relevant regulations including GPP.

Ability to work in a 'virtual' team environment as well as work independently, seeking guidance as appropriate.

Ability to manage complex workload (across multiple studies as necessary) and prioritize accordingly.

Consistently delivers work to 'First Time Quality' whilst managing time effectively to meet metrics and/or team objectives.

Sound problem solving and analytical skills and able to prioritize multiple tasks and achieve study timelines.

Willing to travel internationally as necessary.

Effectively applies knowledge to provide advice or solutions based on expertise and experience.

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Cross References and Citations:

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