

Manager, Study Start Up

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Company: PRA

Location: Netherlands

Category: computer-and-mathematical

ICON plc is a world-leading healthcare intelligence and clinical research organization. We're proud to foster an inclusive environment driving innovation and excellence, and we welcome you to join us on our mission to shape the future of clinical development.

We are looking for candidates based in Belgium or the Netherlands who are speaking fluently Dutch.

GENERAL POSITION SUMMARY:

Working directly with Investigative Sites, this role will manage and perform activities at a site level associated with study start up including regulatory document collection, preparation of ethics submission documents, informed consent review and essential document package review. Reporting to the SAM Line Manager, the Site Activation Manager must have an in depth understanding of study start up activities and associated regulatory requirements.

KEY RESPONSIBILITIES:

Build and cultivate relationships with key study personnel, including Study Coordinators

Work directly with Investigative Sites for all aspects of study start up including: activation timeline development, regulatory document preparation and collection, assisting with IRB/EC submissions and informed consent review

Assist in creation, review and customization of country/site specific Informed Consent Forms (ICFs)

Assist in drafting and responding to IRB queries and facilitating responses to EC queries

Assist in contract and budget negotiations, as necessary

Manage translations of relevant study documents

Proactively identify site challenges and implement appropriate mitigations

Provide regular local status updates to study team and escalated risks to timelines

Manage and track issues and escalations to internal stakeholders

Assist in the development of start up plans

Update study tracking tools and databases with site status

May participate in feasibility and/or site identification activities

Performs other duties as assigned

KEY COMPETENCIES REQUIRED:

Ability to work under pressure to meet deadlines

Self motivated and ability to work well independently and in a team environment

Ability to effectively manage a high volume of multiple priorities

Excellent communication skills (written and verbal) to be able to interact with internal Vertex group: (legal, medical monitors, clinical safety, regulatory affairs and others) as well as external groups (IRBs, Investigators, and others)

Excellent project management skills

Excellent collaboration skills in a cross functional environment

Provides input and executes department initiatives

Meticulous attention to detail and process oriented

What ICON can offer you:

Our success depends on the quality of our people. That's why we've made it a priority to build a diverse culture that rewards high performance and nurtures talent.

In addition to your competitive salary, ICON offers a range of additional benefits. Our

benefits are designed to be competitive within each country and are focused on well-being and work life balance opportunities for you and your family.

Our benefits examples include:

Various annual leave entitlements

A range of health insurance offerings to suit you and your family's needs

Competitive retirement planning offerings to maximise savings and plan with confidence for the years ahead

Global Employee Assistance Programme, TELUS Health, offering 24-hour access to a global network of over 80,000 independent specialised professionals who are there to support you and your family's well-being

Life assurance

Flexible country-specific optional benefits, including childcare vouchers, bike purchase schemes, discounted gym memberships, subsidised travel passes, health assessments, among others

Visit our careers website to read more about the benefits of working at ICON:

<https://careers.iconplc.com/benefits>

ICON, including subsidiaries, is an equal opportunity and inclusive employer and is committed to providing a workplace free of discrimination and harassment. All qualified applicants will receive equal consideration for employment without regard to race, colour, religion, sex, sexual orientation, gender identity, national origin, disability or protected veteran status.

If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or in order to perform the essential functions of a position, please let us know or submit a request [here](#).

Interested in the role, but unsure if you meet all of the requirements? We would encourage you to apply regardless – there's every chance you're exactly what we're looking for here at ICON whether it is for this or other roles.

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