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Principal Statistical Programmer, Single Sponsor - Home Based or Office Based

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Company: Fortrea

Location: Rishon le Tsion

Category: other-general

As a leading global contract research organization (CRO) with a passion for scientific rigor and decades of clinical development experience, Fortrea provides pharmaceutical, biotechnology, and medical device customers a wide range of clinical development, patient access and technology solutions across more than 20 therapeutic areas. With over 19,000 staff conducting operations in more than 90 countries, Fortrea is transforming drug and device development for partners and patients across the globe.

As a Principal Statistical Programmer in our sponsor-dedicated Flexible Solutions business unit, you are central to the successful delivery of complex projects for a renowned, innovative and global top pharmaceutical company. Our sponsor is looking for Principal Statistical Programmers capable of overseeing studies from the Pharma side.

You will be involved in liaising with the entire study team as needed, including Clinical, Medical Writing, Safety and Biometrics. This may be for either/or in-house programmed or out-sourced studies in either their Early or Late Phase team. It is a great opportunity to see more how this works from a Big Pharma perspective, whilst still being part of a global CRO with opportunity for future career growth.

This position allows you to participate in the development of innovative new benchmark drugs for a wide variety of therapeutic areas such **chronic and rare diseases.**

You can be 100% home-based in EMEA or, if you prefer, you can work from our local office in your home country.

What else can you expect from us?

Rewarding and meaningful work in an established, diverse, highly profitable and respected

global company

Highly competitive compensation packages, including various local benefits such as pension contributions, complimentary health insurance plans, remote working allowances etc.

A genuine work life balance

Flexibility in working hours

A thorough onboarding with support from your personal mentor

A permanent employment contract with Fortrea

Excellent training and career development opportunities, as well as support with advancing your individual education

Strong support from your Line Manager and your team, as well as from more than 20,000 Fortrea colleagues worldwide

Main Responsibilities:

Plan, execute and oversee all programming activities on a study, including but not limited to: resource estimation, working within budget, meeting timelines, maximizing quality, interaction with other departments, etc.

Oversee SDTM, ADaM and TLF development, perform Senior Review of outputs

Liaise with other Sponsor departments for additional programming needs, as required to support publications, medical writing and additional development needs and analyses

Support/oversee submission activities (especially in late phase team)

Ensure all activities are conducted efficiently, with appropriate set-up of needed tools and macros, prioritizing quality at all times

Mentor less-experienced team members in best practices around SDTMs, ADaMs and TFLs while ensuring adherence to department standards and processes

Your profile:

Ideally, a degree in a relevant field such as mathematics, life sciences, statistics, computer sciences, etc.

In lieu of the above: professional experience in statistical programming within clinical trials in a biotech, CRO or pharmaceutical company

Solid experience with complex clinical trials (minimum 5 years) and the corresponding datasets' content (safety and efficacy) and endpoints

Ideally you will have knowledge in all aspects of clinical trials, from initial study set-up to study completion, with an understanding of the roles and responsibilities of all related disciplines, e.g. Biostatistics and Clinical Data Management

Expert knowledge of base SAS, SAS macros, SAS/STAT and in debugging SAS programs

Broad knowledge of all CDISC requirements related to SDTM and ADaM, including define.xml, Reviewer's Guides and submission standards

An autonomous, collaborative work style, a curious mind and a keen attention to detail

Fluency in English – both verbal and written – is a must

REMOTE
#LI-AA3
Fortrea is actively seeking motivated problem-solvers and creative thinkers who share our passion for overcoming barriers in clinical trials. Our unwavering commitment is to revolutionize the development process, ensuring the swift delivery of life-changing ideas and therapies to patients in need. Join our exceptional team and embrace a collaborative workspace where personal growth is nurtured, enabling you to make a meaningful global impact.

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