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Sr. Site Monitoring Plan Specialist

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Company: Bristol Myers Squibb

Location: Field

Category: Other-General

At Bristol Myers Squibb, we are inspired by a single vision – transforming patients' lives through science. In oncology, hematology, immunology and cardiovascular disease – and one of the most diverse and promising pipelines in the industry – each of our passionate colleagues contribute to innovations that drive meaningful change.

We bring a human touch to every treatment we pioneer. Join us and make a difference.

The Site Monitoring Plan (SMP) Specialist drives SMP content development and excellence. Acts as the RCO functional representative for Data Management Review Plans, providing input to ensure data integrity and completeness.

Key Responsibilities and Major Duties Serves as the study level global RCO representative for monitoring providing input into the Risk Assessment and other critical study level plans including:+ DQMP (Data Quality Monitoring Plan)+ PDRP (Protocol Data Review Plan)+ CMSP (Centralized Monitoring Strategy Plan) + DLP (Database Lock Plan) + PDAP (Protocol Deviation Assessment Plan) SMP (Site Monitoring Plan) Authoring and Management:+ Drive SMP content excellence, by providing study-specific and detailed guidance for monitoring sites, including on-site and off-site monitoring expectations + At start-up develop and write the study specific SMP and maintain it for the life of the study + Create RBM monitoring execution slide-deck and update for the life of the study + Develop SPSD (Site Process and Source Documentation) Form and update for the life of

the study+ Perform the TSDV specifications quality control check (RAVE), review and approve the TSDV specification in the study Trial Master File. + Attend the relevant study level meetings to support SMP creation, including RACT protocol meeting and Data Review Strategy meeting (e.

g. to understand the critical data requiring SDV) + Support study related RBM questions+ Participate in inspections as needed Management of Targeted Source Data Verification (TSDV) in the Electronic Data Capture (EDC) system at a study level.

May include block/tier changes, subject include, override, and run retrospective triggered by RACT risk level changes, changes to critical data, post productions changes, etc._(Disclaimer: The responsibilities listed above are only a summary and other responsibilities will be requirements as assigned)_**Qualifications, experience and competencies**Our ideal candidate will have a strong Clinical Trial Monitoring background with experience in Risk Based Monitoring & + Bachelors degree required preferably within life sciences or equivalent.

+ At least 3 years of robust site monitoring experience + Prior data management quality review experience preferred+ Knowledge of ICH/GCP Guidelines and applicable local laws and regulations (Health Authorities) which govern clinical trials+ Knowledge and understanding of clinical research processes, regulations and methodology + Understands clinical landscape with practical knowledge of a variety of medical settings and medical records management + Organization and time management skills.

+ Ability to build, maintain and strengthen relationships even under pressure and/ or in difficult situations + Good verbal and written communication skills + independent use of Microsoft Suite, Clinical Trial Management Systems (CTMS), Electronic Data Capture Systems (eDC) & Electronic Master File (eTMF) To protect the safety of our employees, third parties, customers, patients and communities, BMS Australia requires all employees to be fully vaccinated using a locally approved vaccination against COVID-19, unless an exemption is applicable under the State or Federal legislation relevant to you (e.g.

your state’s anti-discrimination act). Within our policy an exemption can only be approved by the HR Director.

By applying for this role, you understand that you will be asked if you can comply with the Policy #LI-RemoteAround the world, we are passionate about making an impact on the lives of patients with serious diseases. Empowered to apply our individual talents and diverse perspectives in an inclusive culture, our shared values of passion, innovation, urgency, accountability, inclusion and integrity bring out the highest potential of each of our colleagues.

Bristol Myers Squibb recognizes the importance of balance and flexibility in our work environment. We offer a wide variety of competitive benefits, services and programs that provide our employees with the resources to pursue their goals, both at work and in their personal lives.

Company: Bristol Myers Squibb **Req Number:** R1564362**Updated:** 2022-11-30 04:04:43.510 UTC**Location:** Field,AustraliaBristol Myers Squibb is an equal opportunity employer.

Qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, age, disability, protected veteran status, pregnancy, citizenship, marital status, gender expression, genetic information, political affiliation, or any other characteristic protected by law.

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