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Associate Director, Clinical Data Management Standards & Systems

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Company: Genmab

Location: Belgium

Category: computer-and-mathematical

The Role
& Department
The Associate Director, Standards & Systems is operationally responsible for the development, maintenance and adherence to Genmab's clinical data standards including eCRFs, edit checks, controlled terminology, CDASH and SDTM mapping and etc. The role provides leadership for the continued development and enforcement of data standards through extensive collaboration with Data Management, Clinical Programming, Medical, Stats and other cross-functional teams where needed. This role works to implement data standards after an extensive upstream/downstream impact is assessed, maintaining consistency with related supportive processes to ensure accurate and seamless use of end-to-end Genmab standards. This role will also support our Systems team as administrative support for our standalone JReview system and assist with the implementation of a Genmab specific URL in Medidata Rave. Prior experience working in Medidata Rave in the core configuration environment or system implementation is preferred. SAS programming experience or experience programming custom functions is advantageous.

Responsibilities:

- Lead and participate in the development and maintenance of global clinical data standards, CDASH/SDTM mapping, controlled terminology, non-CRF standard data mappings (e.g., lab or ECG), and other applicable industry standards.

Primarily responsible for the database design, setup, and maintenance of assigned clinical trials/projects in Medidata Rave.

Ensure that all study builds are aligned with the necessary standards and guidelines.

Collaborate with other teams and departments to ensure the seamless execution of clinical trial projects.

Stay updated with the latest advancements and updates within the Medidata Rave platform and incorporate them into the study builds as necessary.

Develop and coordinates training for data management staff and other impacted functions on changes to global standards library and/or enhancements in data managements systems.

Define, manage and govern clinical data standards; as required.

Contribute to the development of best practices/SOPs within Genmab Standards, aligned with industry and regulatory best practices.

Support filing and submission readiness activities; ensure alignment with regulatory requirements.

Participate in relevant study and project team meetings as the Standards Technical SME and provide input for standards components, such as CRF design, CRF Completion Guidelines, programmed edit checks, SDTM mapping specifications and SDTM annotated CRF.

Act as a consulting resource for project teams regarding eCRF development, which may include output from industry standard software tools and Genmab custom validation programs including Metadata Repository, change request systems, and issues tracking systems.

Coach Cross functional teams and vendors on Genmab data standards and related processes.

Communicate and reinforce content and interpretation of Genmab data standards to project and study teams, to ensure consistency in understanding and implementation of

standards across a project and/or program.

Participate in data standardization initiatives to ensure protocols comply with portfolio-level standards, CDSIC standards, SOPs and regulatory requirements.

Experience multi-tasking and project management experience a must.

Requirements - what you must have:

Bachelor's degree in science or related area 10+ years of significant Standards Experience and/or Clinical Data Management (CDM) experience in biotech/pharma industry, hands-on experience in all aspects of data activities.

Experience in oncology trials with an understanding of the complex and interdependent relationships between protocol development, data collection and analysis and reporting.

Significant Experience in the use of data management systems, strong knowledge of CDM processes, tools, methodologies, documentation, and strong understanding of CDM data collection strategy.

Experience working with GCPs, SOPs, regulatory requirements, and good data management practices.

Experience with CDISC (SDTM); data collection requirements in oncology trials; and clinical data standards development and maintenance.

Experience in pharmaceutical industry CDASH/SDTM data standards management and implementation required.

Demonstrated experience in all phases of drug development and clinical research in multiple therapeutic areas.

Demonstrated knowledge of industry standards (CDISC), FDA & ICH, GCP, and related regulatory requirements

Knowledge of SDTM best practices and tools (such metadata repository, global librarian) and has a track record in applying own knowledge to significantly improve efficiencies.

Ability to work in a fast-paced environment and be influential in reaching prompt decisions

to support accelerated clinical trial development.

Demonstrated experience managing multiple tasks, complex projects and working with cross-functional teams delivering to project timelines and metrics.

Significant experience in project management.

Experience working on early and late-stage submissions as per local/regulatory requirements.

Equivalent combination of education and experience or certification in assigned area.

Experience in Biotech/Pharmaceutical industry preferred.

Experience in Oncology standards (solid tumors and hematology) preferred.

Where you will work

This position can be based in Princeton, NJ USA and is hybrid. For US-based applicants who are not in commuting distance to Princeton but within US Eastern or Central Time Zones, we can consider remote applicants.

This position can also be based in the Utrecht, Netherlands or Copenhagen, Denmark offices and is hybrid. Genmab will additionally consider applicants from Belgium and be remote.

For US based candidates, the proposed salary band for this position is as follows:

$,.00---$,.00

The actual salary offer will carefully consider a wide range of factors, including your skills, qualifications, experience, and location. Also, certain positions are eligible for additional forms of compensation, such as bonuses.

About You

You are passionate about our purpose and genuinely care about our mission to transform the lives of patients through innovative cancer treatment

You bring rigor and excellence to all that you do. You are a fierce believer in our rooted-in-science approach to problem-solving

You are a generous collaborator who can work in teams with diverse backgrounds

You are determined to do and be your best and take pride in enabling the best work of others on the team

You are not afraid to grapple with the unknown and be innovative

You have experience working in a fast-growing, dynamic company (or a strong desire to)

You work hard and are not afraid to have a little fun while you do so

Locations

Genmab leverages the effectiveness of an agile working environment, when possible, for the betterment of employee work-life balance. Our offices are designed as open, community-based spaces that work to connect employees while being immersed in our state-of-the-art laboratories. Whether you're in one of our collaboratively designed office spaces or working remotely, we thrive on connecting with each other to innovate.

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