Overview:

Working with the CDISC Terminology lead, CDISC team members and the CDISC volunteer and clinical research community, the **Terminology Specialist** will support key standards development projects under the CDISC Controlled Terminology Program, particularly around development of disease-specific terminology and definitions.

Reports to:

CDISC Manager responsible for Terminology Activities

Location:

CDISC offices are based in Austin, TX. However, applicants for this contractor position may work from their home offices. The contractor may need to travel up to 3 times per year for certain team meetings.

Accountabilities of Position:

- Facilitate and support terminology development and harmonization projects relevant to core CDISC standards for data collection, analysis and regulatory submission with team members, key global business partners and pharmaceutical stakeholders as needed (e.g., US FDA, NCI, Pharmaceutical Companies, Academic Institutions).
- Process and follow-up on all new terminology requests submitted through the CDISC Terminology Request Form.
- Research online terminology resources, dictionaries to identify inputs or candidate terminology systems that may be reused for specific clinical research standards use cases.
- Create terminology “packages” ready for public review and coordinate responses to all public review comments.
- Plan for and facilitate audio conferences, face-to-face meetings and team communication, including the distribution of agenda/meeting objectives, creation and distribution of meeting minutes with follow-up actions items.
- Follow-up on outstanding action items with team members to ensure that team milestones and deliverables are met in the appropriate timeframe.
- Assist in the identification of best practices, lessons learned and the evaluation and improvement of terminology development processes.
• Adhere to all CDISC policies and procedures, including the Code of Ethics and the Intellectual Property Policy.

Qualifications:

• Bachelor’s Degree in a relevant discipline, including, but not limited to Life Sciences, data management or relevant health-related fields.
• Familiarity with clinical data and terminologies, include Clinical Research experience (Pharmaceutical Company, Biotech, CRO, Research Site) or Healthcare experience (Physician Assistant).
• Demonstrated ability to interact with diverse project teams with excellent meeting/team facilitation skills across diverse and geographically dispersed teams (clinicians and technicians).
• Excellent organizational, problem-solving, listening, oral and written communication skills, including familiarity with health or life sciences information, understanding of the clinical development process and acute attention to detail.
• Demonstrated proficiency with the use of personal computers and office applications.
• Proven ability to adapt quickly to new clinically focused projects and work knowledgably with scientific or medical terminologies.

Experience (Preferred):

• If not based in Austin, ability to work in a virtual environment remotely located from supervisor
• Experience in one or more Therapeutic/Disease-specific areas (e.g. Cancer, Cardiovascular Disease, Neurological Disorders, other disease areas)
• Exposure to CDISC standards and standards specifications
• Knowledge or experience with standard terminology systems such as MedDRA, SNOMED, ICD-9/10, LOINC, NCI-EVS, CDISC terminology, etc.

Leadership Skills:

• Creative self-starter and life-long learner open to new ideas and able to work with minimal supervision in a challenging, fast-paced technical environment.
• Team player that values co-operation and collaboration.
• Demonstrated ability to manage and motivate a team to achieve their mission and objectives and develop consensus decisions according to plan.
• Ability to work well with volunteers and make certain that volunteer’s time is well spent by ensuring that meetings are well organized, goal oriented and enjoyable.
• Demonstrated negotiation and interpersonal skills, ability to encourage open discussion, conflict resolution, and consensus building.