Senior Principal Clinical Data Standards Specialist

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REQ-10020532
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Inde

Résumé

The Senior Principal Clinical Data Standards Specialist is responsible for leading the planning, development and implementation of Industry (CDISC and regulatory) compliant Clinical Data Standards, providing expert support to business users and teams on their use and in line with the Clinical Data Standards strategy.
They provide expert support ensuring the development, implementation and timely availability of consistent, high quality Clinical Data Standards deliverables supporting the acquisition and tabulation and/or analysis and reporting of Clinical Trial data across global libraries including.
• Data collection tools in EDC (CRFs, edits checks, derivations, core configurations) and data transfer specifications
• Analysis data/TFL standards
• Associated standard metadata, business rules and guidelines.

About the Role

Major accountabilities:

- Lead and contribute to Clinical Data Standards planning, definition, development, validation and support within assigned standards discipline (domain) including the development and maintenance of associated metadata, documents, business rules and guidelines where applicable.
- Serves as the primary contact for global data acquisition and tabulation, analysis or data submission standards for core global and/or assigned Therapeutic Area ensuring timely and quality deliverables.
- Define and deliver to robust, priority driven standards development plans for assigned area to ensure agreed deliverables are met and assigned resources are fully and effectively utilized.
- Accountable for driving the efficient, high quality and timely implementation of new standards and/or updates to standards
- In collaboration with representatives across Data Operations disciplines and key stakeholder and partner functions within GDO and across Global Drug Development, lead the accurate translation of scientific and analytical requirements into efficient, compliant standards.
- Support and ensure the appropriate and efficient governance and approval of global and project/study specific clinical data standards liaising with governance boards as needed.
- Lead the technical review and assessment of industry and regulatory standards and guidelines supporting regular gap/impact analysis and implementation of action plans where needed.
- Communicate effectively with the partners and customers; Establish and maintain strong collaborative relationships with Data Operations, Biostatistics and Clinical Development groups supporting the development and use of Clinical Data Standards.
- Lead and contribute to the development, maintenance and training of relevant clinical standards systems and processes.

- Act as an expert consultant providing Clinical Data Standards input to all relevant areas including; electronic data capture/database programming, edit check programming, report programming, electronic data loads, IVR technology, electronic patient reported outcomes, metadata management and/or other clinical data management or analysis data and TFL-related systems.
- Act as primary subject matter expert (SME) for assigned area providing support, consultation and training to end users and SME networks on implementation of standards and related tools on development programs.
- Provide mentoring and technical guidance to Clinical Data Standards associates; Contributes to the effectiveness and development of talent.
- Maintain up-to-date, advanced knowledge of relevant technologies (EDC, software languages, applications etc.), Industry Standards (e.g. CDISC, define.xml, eCTD etc.) and regulatory guidelines.
- Represent Novartis within industry wide associations and working groups; contributing to regulatory guidelines, industry practices and professional standards development organizations such as CDISC, CFAST, PhUSE CSS, DIA etc.
- As needed, act as a Clinical Standards representative leading and supporting data standards governance, process improvement initiatives and/or other non-clinical projects.

Key performance indicators:

- Achieve overall goals as set each year by Group Head Clinical Standards.
- Achieve high level of quality, timeliness and customer satisfaction on Clinical Data Standards activities and deliverables.
- Achieve high levels of effective collaboration, customer satisfaction on support and training provided within discipline/area.
- Achieve minimal number of post-production changes resulting from Clinical Data Standards issues.
- No critical findings as result of routine audits or health authority inspections relating to activities/deliverables supported by the Clinical Standards Group.

Minimum Requirements:

· BS/BA/MS in computer science, management information systems, health sciences, statistics, or related field.

· At least 8 years industry experience in one of the following fields- EDC development and implementation preferably using Medidata-Rave or Data Management Clinical or Statistical Programming using SAS and CDISC data standards

· Advanced knowledge in one or more area of industry data standards and requirements including data acquisition, CDISC (CDASH, SDTM, ADaM), reporting and analysis, regulatory data submission.

· Significant experience in supporting development of clinical standards and associated guidelines

· Advanced understanding and knowledge of regulatory requirements and industry standards relevant to data management and statistical programming (including GCP, ICH)

· Excellent project management and coordination skills; Excellent problem-solving, negotiation and conflict resolution skills.

· Outstanding interpersonal and written and oral communication skills, with the ability to effectively communicate cross-functionally.

· Excellent understanding of drug development, global clinical trial / project practices, procedures,

methodologies.

· Proven ability to provide and coordinate internal and external training (Experience working in highly matrix teams and providing technical guidance).

Experience contributing to non-clinical initiatives requiring Clinical Standards expertise highly preferable

Work Experience:

- Functional Breadth.
- Cross Cultural Experience.
- Managing Crises.
- Collaborating across boundaries.
- Operations Management and Execution.

Skills:

- Automation.
- Biostatistics.
- Clinical Trials.
- Computer Programming.
- Metadata Management.
- Statistical Analysis.

Languages :

- English.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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