Patient Data Specialist

Hiring organization
Candidate-1st

Employment Type
Full-time

Beginning of employment
asap

Job Location
Remote, Slovakia

Working Hours
40

Base Salary
euro USD 64K - 93K *

Date posted
May 19, 2024

Description

We are seeking Patient Data Specialist to join our team!

This is a remote based opportunity. We offer flexible location options and remote based working in one of the following countries: Hungary, Serbia, UK, Spain, Romania, Slovakia or Poland.

At Precision for Medicine, we believe that the era of one-size-fits-all medication is giving way to a next generation of treatments, medicines that will be more effective because they are prescribed according to the unique biology of an individual patient. Our mission is to help innovative biotech and pharmaceutical companies accelerate the development of these life-changing treatments. Precision does this by developing assays that utilize biomarkers to help identify the right patient for the right drug. We handle every aspect of clinical trials from initial strategy and design to selecting sites and executing quality clinical trials.

The Patient Data Specialist will perform early and continuing scientific review of clinical data in various formats by applying the protocol and/or other applicable references along with oncology standards for the indication being studied to support overall data quality and consistency (clinical sense of the data) allowing for insights to support a continuous risk management approach.

Essential functions of the job include but are not limited to:

- Serves on assigned project team(s) reviewing subject data for accuracy per protocol, associated references and oncology standards of care and principles to support overall data quality and consistency (clinical sense of the data)
- Develops and maintains a good working relationship with internal and external project team members, serving as an ambassador to promote Precision’s high quality and ethical image in accordance with the company Core Values
- Collaborates with and is supported by management as well as the Medical Monitors to support cross functional departmental communication as applicable on data capture / review trends (e.g., Medical Monitoring, Safety, Clinical Operations, Project Management, Data Management, SAS Programming, Biostatistics, Translational Science, other vendors, etc.) to meet project deliverables in compliance with GCP/ICH, the protocol, oncology standards and applicable Project Plans and SOPs
- Provides input into project related documentation such as EDC specifications and related completion guidelines, Data Review Guidelines, etc. and requires patient review to be coordinated and tracked with other departments as applicable (data management, medical, safety etc.).
- Supports the development and User Acceptance Testing (UAT) of data outputs with Programming (e.g., Smart Patient Profiles, metrics/trackers, listings)
- Requires the use of various EDC systems and data visualization tools
- Assists Management by serving as a resource for project teams regarding scientific, clinical, oncology related questions supported by Medical Monitoring
- Provides routine status updates on findings and escalates issues as

appropriate with project team and Management
- Assists with identification of quality risks and issues and recommends corrective action plans as needed to address deficiencies in performance throughout the life of the project
- Conducts UAT of programming output and participates in EDC UAT supporting the functionality as applicable
- Assists Management to provide review of the protocol from a scientific-operational perspective
- May provide indication input into data capture and other clinical trial document development (e.g., EDC specifications, completion guidelines, edit checks, review guidelines, etc.)
- Assists in the development and implementation of strategy for an integrated data cleaning process between all applicable departments (e.g., data management, medical, safety, vendors, sponsor, etc.)
- Reviews and analyses clinical trial data sources early and ongoing throughout the trial to ensure consistency, integrity and accuracy based on project specific review guidelines with an emphasis on scientific and clinical sense (e.g., adherence to applicable disease assessment criteria).
- Issues and resolves queries in various EDC systems
- Communicates effectively with the internal and external project team as applicable and management to relay data quality issues/findings and implements necessary actions in response to those issues (e.g., CRA and/or site re-training)
- Provides study-specific training for project teams to ensure accurate and consistent collection including re-training as applicable based on review findings
- Develops applicable study-specific monitoring/CRA and data review tools as applicable
- Participates as applicable in internal and external study-specific team meetings
- Serves as a resource to the project team for scientific questions regarding data capture
- May review dictionary coding
- Establishes task tracking metrics to monitor trial and team progress towards project goals
- Provides routine Project Management updates at macro and micro level
- Ensures applicable eTMF documentation related is provided and managed including version control of owned documents
- Performs other duties as assigned by management

Qualifications:

Minimum Required:

- Bachelor’s degree or equivalent combination of education/experience in science or healthcare discipline with proficiency in medical terminology

Other Required:

- At least two (2) years in clinical operations and/or, data management or related discipline in either the CRO or pharmaceutical industry and/or experience conducting oncology clinical research as a Study Coordinator, Research Nurse or related discipline, or equivalent, relevant experience and/or demonstrated competencies.
- Experience as a Clinical Research Associate (CRA) or Study Coordinator/Research Nurse preferred.
- Oncology therapeutic experience required with ability to apply working

knowledge (e.g., understanding of clinical and oncology standards of care and associated side effects, biomarkers, etc.).
- Experience in the review of data from oncology clinical trials with working knowledge of oncology standards (e.g., application of tumor response criteria, CTCAE criteria, etc.).
- Experience in phase I, II and III oncology (hematologic and/or non-hematologic tumors) preferred.
- Experience with electronic data capture systems (EDC) and data visualization tools preferred
- Computer proficiency
- Working knowledge of FDA & ICH/GCP regulations and guidelines.

Preferred:

- Medical related degree, RN, OCN, RPH, PharmD, etc.

Competencies and Skills:

- Expected to be able to work remotely with the ability to apply oncology and clinical trial knowledge to the review of subject data with minimal supervision.
- Demonstrates a working knowledge of oncology with demonstrated ability to apply this knowledge to various tumor types and oncology standards of care (e.g. proficiency in the application of CTCAE, indication specific treatment guidelines, disease assessment criteria such as RECIST, iRECIST, RECIL, IWG, etc.)
- Demonstrates the ability to understand oncology clinical trials methodology, including a working knowledge of protocols and specific indications being studied
- Desire to continually learn and keep up to date on oncology standard of care
- Resolves project related problems and prioritizes workload to meet deadlines with minimal support
- Adaptable / Flexible (willing and able to adjust to multiple demands and shifting priorities; ability to meet day-to-day challenges with confidence and professionalism)
- Demonstrates an acceptable degree of professionalism, as evidenced by punctuality, ability to deliver on commitments, an understanding of the service culture and positive interactions with customers and teammates, including good interpersonal skills
- Proficient critical thinking, problem solving and decision making skills with attention to detail
- Professional use of the English language in both written and oral formats
- Demonstrates, an understanding of the service culture
- Strong sense of teamwork
- Exhibits high self-motivation, and is able to work and plan independently as well as be highly effective in a remote team environment
- Ability to assimilate clinical and technical information quickly
- Demonstrates a high level of emotional intelligence
- Possesses practical knowledge of IT tools and systems including proficiency in Microsoft Office: Word, Excel, PowerPoint, Outlook, EDCs, EMRs and data visualization tools.
- Values system and work ethic consistent with Precision Values and Company Principles.
- Ability to drive and travel up to 25% domestically and internationally including overnight stays

Precision medicine is revolutionizing the attack on cancer—and we are passionate about helping you harness its power. We strike tumors on a molecular level using biomarkers to link specific mutations to specific treatments. We combine deep science with deep data from advanced technological platforms, then layer on specialized expertise in the design and execution of targeted, adaptive clinical trials. Ultimately, we deliver robust insights that inform real-time decisions—and optimize the oncology development pathway.

#LI-NC1 #LI-Remote

Any data provided as a part of this application will be stored in accordance with our Privacy Policy. For CA applicants, please also refer to our CA Privacy Notice.

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If you are an individual with a disability and require a reasonable accommodation to complete any part of the application process or are limited in the ability or unable to access or use this online application process and need an alternative method for applying, you may contact Precision Medicine Group at QuestionForHR@precisionmedicinegrp.com.

How the process will look like

Your teammates will gather all requirements within our organization. Then, once priority has been discussed, you will decide as a team on the best solutions and architecture to meet these needs. In continuous increments and continuous communication between the team and stakeholders, you're part of making data play an even more important (and understood) part withing Brand New Day.

Job Benefits

USD 64K – 93K *