Clinical Biospecimen Senior Scientist

Job ID
REQ-10010893

9月 03, 2024

Japan

摘要

ノバルティスのプロセス、規制および倫理的要件に準拠し、薬物動態、バイオマーカー、安全性等に関わる生体試料の収集に関して、臨床試験へ実装し、臨床試験開始から終了までのOperationを担当します。また、コンパニオン診断に関連する業務についてもサポートする場合があります。

Responsible for the implementation and end-to-end operational execution of each GCO clinical trial strategy as it relates to all biospecimens collected, including safety, pharmacokinetics, biomarkers for clinical trials of standard to medium complexity, in compliance with Novartis processes and regulatory and ethical requirements. May support specific aspects related to companion diagnostics.

About the Role

Major Accountabilities
> Lead Clinical Biospecimen

Scientist(CBS)の監督
下、社内関係者と協働し
、戦略に基づき、臨床試験における
生体試料に関する技術面・Operation
に関連する業務を実行する。主に以下の業務を実施する。

- 臨床試験関連文書（治験実施計画書や同意説明文書
などの臨床評価　項目に情報を提供する。

-
臨床試験固有のサンプル収集表を作成する。また、ラボマニュアルなどの関連文書も
含め、ラボキットの作成、サ
ンプルの管理、検査会社（ Laboratory)に対して技術的側面を管理する。

- 生体試料のライフサイクル全体を通じて、サンプル管理処(分含む)輸送を担当
する。社内関係者および検査解析会社（ Laboratory
)と協働し、症例報告書C(RF)とデータ転送に関する要件を定義し、
タイムリーな分析、転送されたデータの品質を担保する。

> Risk management:
社内関係者と協力し、生体試料の収集および分析に関連する臨床試験固有のリスクお
よび問題を適切に報告する。

> Resource management: Lead CBSの監督の下、 Vendor
managerおよびProcurementと協力して、検査会社（ Laboratory
)からの提案、予算情報、および請求書の確認をおこなう。

>
担
当臨
床試験および担当プログラムにおいて、標準業務手順書S(OP)を遵守し、 Lessen
and Learnなどを通じて最良の結果を求める。

Key Performance Indicators
> GCP, SOP, ICH等の遵守
> 社内関係者、および臨床試験チームからインプットをもらい、期限内にサンプル輸
送ができる体制を整える 。

> 担当臨床試験において、効率的な代替案およびリスク軽減計画を含む業務計画を策
定し、生体試料関連業務の適時、効率的かつ高品質で実行する。

> 設定された期限内に、臨床試験固有の文書の作成またはサポートをする。

Experience/Professional requirements
> 標準的な検査方法、分析方法、および分子生物学に精通

> 臨床検体の取扱いに2年以上の経験があること

> 臨床試験デザインと医薬品開発プロセスに関する知識
> GCP, GLP, ICHの知識

> コミュニケーション、コラボレーション、優先順位付け

Language
英語

Accountabilities

1. With some oversight from the lead Clinical Biospecimen Scientist (CBS), contribute to all technical and operational biospecimen-related matters for assigned clinical studies of standard to medium complexity, in collaboration with internal stakeholders and line function (LF) representatives.

- Provide input on clinical sample assessment sections in clinical trial-related documents (such as protocols and consents) in collaboration with the LF representatives.
- Create study-specific sample collection tables and ensure alignment with blood volumes needed versus allowed.
- Liaise with internal stakeholders to provide input into the SSW ' s for all biospecimen collection and testing needs.
- Responsible to set up and oversee the technical aspects for all laboratories involved in kit building, sample management, and testing, including all related documentation such as lab manuals.
- Provide input and solutions on the ethical considerations for biospecimen collections and analyses for protocols and consents to ensure that all specific processes needed for approval in different countries are implemented.
- Responsible for sample management and logistics, with some oversight from the Lead CBS, throughout the biospecimen lifecycle; this includes ensuring timely analysis, proper consent, and oversight of samples, in collaboration with data management.
- Define sample needs for the case report forms (CRFs) and data transfer in collaboration with internal stakeholders/LF representatives, trial clinical data scientist (TCDS) and analysis labs; With support, liaise with the TCDS and labs for data transfer and data reconciliation.
- Collaborate with internal stakeholders to establish analytical plans and review transferred data to ensure quality.
- Support the development of training material on the technical aspects of biospecimen collections for the clinical trial sites, including study specific lab manuals and additional site and monitor training needs.
- Ensure proper handling of all study close out activities related to biospecimens and laboratories, including sample disposition (disposal, return, storage).

2. Risk management:

- Ensure proper escalation of any identified trial specific risks and issues related to biospecimen collection and analysis in conjunction with relevant line functions.

3. Resource management:

- In collaboration with vendor management and procurement, with some oversight from the Lead CBS, review all laboratory proposals and provide budget input for the trial forecast; review invoices.
- In collaboration with vendor management, manage relationships with labs.

4. Responsible for implementation of and compliance to standards (SOPs) and best practices within assigned clinical trial(s) and within clinical program(s), including sharing lessons learned.

Education (minimum/desirable):

Advanced degree in life sciences strongly preferred, BS or BA in life sciences with relevant experience required

Languages:

English

Experience/Professional requirements:

- Familiarity with standard sample testing methodologies, assay technologies, and molecular biology
- At least 2 years of experience handling diverse type of clinical samples
- Knowledge of GCP; intermediate knowledge of GLP and ICH
- Intermediate knowledge of clinical trial design and the overall drug development process
- Excellent organizational and communication skills
- Ability to manage multiple competing priorities and meet timelines

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部門
Development

Business Unit
Innovative Medicines

地点
Japan

站点
Head Office (Japan) (Pharmaceuticals)

Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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