Clinical Biospecimen Senior Scientist

Job ID
REQ-10010893
Sep 03, 2024
Japón

Resumen

Operation

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)
Operation

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- Laboratory

- Laboratory CRF

> Risk management:

> Resource management: Lead CBS Vendor manager Procurement Laboratory

> SOP Lessen and Learn

Key Performance Indicators
> GCP, SOP, ICH
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Experience/Professional requirements

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> GCP, GLP, ICH

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Language

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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