NOVARTIS

Associate Submission Manager

Job ID
394848BR
Mai 02, 2024
Inde

Résumé

Our Biomedical Research (BR) Submission Management team provides operational and logistical support to Translational Medicine (TM) preclinical and early phase clinical teams focussing on the preparation of deliverables in support of filings to regulatory authorities. Thereby, ensuring TM functions maintain a high level of compliance with established standards, practices, and regulatory requirements.

About the Role

Your responsibilities include, but are not limited to:

- Manage activities associated with the preparation of non-oncology Investigator Brochure (IB) annual updates within Biomedical Research (BR) in compliance with internal SOP and health authority requirements.
- Organizing and chairing the kick-off meeting to establish the level of update and contributors across Biomedical Research Translational Medicine and Development.
- Leads subsequent IB planning discussions, creating, and maintaining a comprehensive project plan capturing actions and key activities, target governance board review, content delivery timelines, and finalization date for IB.
- Manage stakeholder engagement, and ensure that any issues, risks, or impact due to changes in strategy and/or timelines are assessed quickly and remediated.
- Timely escalation (as per agreed process) if the IB will not be finalized within the annual update period.
- Collaboration with Document Quality Management (DQM) team and other key stakeholders e.g. Regulatory Operations to ensure strategic resource planning of downstream activities allowing IB to be finalized in accordance with targeted timelines. Completion of all internal documentation and distribution of the final IB package in accordance with SOP and internal guidance.
- Timely update of all internal tracking systems.
- Manage submission related activities associated with the preparation of Clinical Trial Application submissions following internal working practice, guidance, and SOPs to ensure the delivery of high-quality submission documents to regulatory operations.
- This may include creation of requisite templates, drafting of timelines, ensuring documents are finalized according to internal process via source data verification and formatting checks in accordance with agreed timelines, and stakeholder management.
- Manage the preparation of Biomedical Research components (preclinical and early phase clinical) of supplementary submissions.
- May distribute workload to and collaborate with external vendor on documentation specific activities.
- Regularly maintain supporting IT systems/trackers to ensure accuracy of information by liaising with stakeholders.

- Relevant work experience (1-2 years) in regulatory documents and associated submission processes and basic understanding of submission deliverables i.e., non-clinical and/or clinical
- Comprehensive understanding of relevant technical requirements for electronic registration submissions (eCTD) e.g. Bookmarking, hyperlinking, cross referencing etc.
- Demonstrated ability to work successfully within a matrix environment and influence cross functional teams.
- Experience with and ability to understand compliance practices which include GxPs and Standard Operating Procedures
- Proficient in Microsoft Office suite in addition to SharePoint.
- Strong oral and written communication skills and customer service skills and organizational skills.
- Self-starter with a proven ability to prioritize work, multitask, display customer centricity, and manage time appropriately, in a fast paced/high volume environment. Demonstrated organizational skills.

WHY NOVARTIS

769 million lives were touched by Novartis medicines in 2020, and while we're proud of this, we know there is so much more we could do to help improve and extend people's lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could do here at Novartis!

Commitment to Diversity & Inclusion:

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

Join our Novartis Network : If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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Business Unit
Pharma Research

Emplacement
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Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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