

Associate Submission Manager

Job ID
394848BR
Mai 02, 2024
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Summary

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.

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