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Submission Manager

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Company: Novartis India

Location: hyderabad

Category: other-general

Position Title : Submission Manager

About The Role

Responsible for contributing to the planning, coordination, development and timely delivery of high quality Clinical submission documents to Regulatory Affairs (RA) for

New Drug Applications (NDA) , Biologic Licensing Applications (BLA), Marketing Authorization Applications (MAA) and supplemental NDAs/BLAs/ Type II variations, for related follow-up activities (e.g. Safety Updates, answers top Health Authority (HA) questions).

YOUR KEY RESPONSIBILITIES:

Your responsibilities include, but are not limited to:
Provide cross-divisional Clinical submission contributions and serve as content/technical contributor for Clinical submission document requirements for assigned programs supported by Submission Management Department.
Contribute to the global cross-functional Clinical Submission Team to ensure all Clinical submission documents are delivered in accordance with timelines, high quality, operational and technical procedures; report Clinical submission progress and issues with a resolution plan to

Group Heads of Submission Management, Regulatory Affairs and other relevant line units Heads,as needed.

Contribute to the Clinical Submission Planning Meeting with cross functional team members to define Clinical submission content, data pooling strategies for summary documents (e.g. Summary of Clinical Efficacy (SCE) and Summary of Clinical Safety (SCS)) and identify full Clinical Submission Team composition; provide meeting agenda and meeting minutes.

Facilitate definition of delivery schedule and batch content for statistical outputs and medical writing strategy ensuring continuous receipt, review and integration into Summary Documents (e.g. SCE, SCS and Clinical Overview (CO)).

Contribute to the identification of all Clinical submission deliverables (including all relevant trials); negotiating and tracking timelines, accountabilities and responsible individuals assigned, in collaboration with Clinical Submission Team members for HA filings; include on RA submission tracker and maintain with real-time updates.

Identify issues and potential resource gaps effecting preparation and delivery of Clinical submission documents across line functions; negotiate and implement solutions.

Contribute to pre-submission Health Authority briefing books.

Co- facilitate extended Clinical Submission Team meetings to synchronize submission messages with Senior Management at:

a. Clinical Submission Team Kick-off – goal is to ensure clear submission strategy and early target labeling messages endorsed by Senior Management and understood by all Preclinical and/or Clinical submission team members; all contributing line units present proactive assessment of key issues and actions within their lines which will effect timely delivery of Preclinical and/or Clinical submission documents. Agenda and meeting minutes issued by Submission Manager (SM).

b. Key Message Harmonization Meeting – goal is to ensure Senior Management and cross functional development departments are aligned on key efficacy, safety, Biopharmaceutics and Clinical Pharmacology messages following receipt of key pooled Clinical data. Agenda and meeting minutes issued by SM. Meeting cofacilitated with RA.

Lead or contribute to regularly scheduled Clinical Submission Team meetings, provide agenda, minutes and updates to deliverable timelines; ensure timelines are in accordance

with Novartis processes

Represent Clinical Submission sub-team at RA Core Submission Team Meetings and RA submission team operations' meetings (providing status updates/presenting issues and mitigation plans), as applicable

In collaboration with the Clinical authors (e.g. Global Program Medical Director, Program Statistician, Brand Safety Leader, etc.) co-facilitate SCE and SCS Data Analysis Review Meetings to align analysis interpretation of these Clinical summary documents for inclusion into the SCE and SCS draft reports as applicable

Co-facilitate Summary Document Report Review Meetings to aid in the development of these documents from draft to content final in collaboration with Medical Writers and Clinical Authors via direct team interaction and dialog (e.g. teleconference, videoconference, or face to face); facilitate obtaining final approval from Clinical, Analytics, Safety and RA Therapeutic Area Heads.

Contribute to the authorship of the following (but not limited to), supportive Clinical submission documents (as appropriate to the submission); ensuring content and technical compliance with International Conference on Harmonization (ICH) and local Health Authority guidelines:

a. CTD 1.3.4. Financial Disclosure Certification

b. CTD 1.4.3. Information about the experts - clinical

c. CTD 1.9. Information relating to clinical trials

d. CTD 2.7.5. List of references

e. CTD 2.7.6. Synopsis of Individual Studies

f. CTD 5.2 Tabular Listing of All Clinical Studies

g. CTD 5.3.7. Statement on CRFs and individual listings

Co-facilitate discussion and proactive preparation with relevant Clinical submission team

members for summary Clinical site information supporting FDA Office of Scientific Investigations (OSI) Inspections for each FDA submission or information supporting EMA accelerated assessment
Contribute to the validation checks of RA cross reference links established for all managed Clinical Submission deliverables within the Common Technical Document (CTD) prior to Health Authority dispatch.

Role Requirements

WHAT YOU'LL BRING TO THE ROLE:

Minimum university higher degree in life sciences/healthcare or equivalent with ≥ 2 years' experience in Clinical research with proven proficiency in global Clinical development.
Fundamental leadership of cross-functional teams. Has demonstrated teamwork, communication and Organizational skills. Works effectively and is able to establish relationships with other line functions
Strong working knowledge in world wide regulatory requirements for drug registration (e.g., Common Technical Document)
Previous experience in medical writing, Preclinical and/or Clinical submissions, and interactions with health authorities is preferred
Solid computer technical skills (Word / Excel / Power-point/MS Project) and ability to learn new systems quickly

Why Novartis?

766 million lives were touched by Novartis medicines in 2021, 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!

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

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