

Senior Medical Information Manager 2

Job ID 390368BR Apr 23, 2024 Ireland

About the Role

Major accountabilities:

- To author and review high quality clinical and safety documents: non-registration clinical Study Reports (CSR), Development safety Update Reports (DSUR), Risk Management Plans (RMP) -Core member of clinical Trial Team/participate in safety Management Team -Actively participate in planning of data analyses and presentation used in CSRs.
- Act as documentation consultant in CTTs and SMTs To ensure compliance of documentation To internal company standards and external regulatory guidelines.
- May Act as Program Writer ensuring adequate medical writing resources are available for assigned Program and consistency between documents.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

• Delivery of high quality clinical and safety documents in time and in compliance with internal and external standards -Customer / partner/ project feedback and satisfaction -Adherence to Novartis policy and quidelines

Minimum Requirements:

Work Experience:

- Cross Cultural Experience.
- Operations Management and Execution.
- · Functional Breadth.
- Collaborating across boundaries.

Skills:

NA.

Languages:

• English.

Role Requirements

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

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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

Division Operations **Business Unit** CTS Location Ireland Site Dublin (NOCC) Company / Legal Entity IE02 (FCRS = IE002) Novartis Ireland Ltd **Functional Area** Research & Development Job Type Full time **Employment Type** Regular Shift Work No Apply to Job

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