

# Senior Medical Information Manager 2

Job ID  
390368BR  
Apr 23, 2024  
Ireland

## Summary

-To write, review and/or manage the production of high quality clinical and safety documentation for submission to regulatory authorities in support of marketing applications. To provide documentation related consultancy to other line functions.

## 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 guidelines

### Minimum Requirements:

#### Work Experience:

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

#### Skills:

- NA.

#### Languages :

- English.

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

Division

Operations

Business Unit

CTS

Location

Ireland

Site

Dublin (Novartis Corporate Center (NOCC))

Company / Legal Entity

IE02 (FCRS = IE002) Novartis Ireland Ltd

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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