Discovermore

Clinical Development & Safety Associate

Department: R&D
Hours per week: 37.5
Basis: Permanent

Job Purpose

To support the Clinical Science Team in all relevant activities and act as liaison with the ATL Pharmacovigilance Team.

Key Responsibilities

- To support the Clinical Development Physicians in the execution and delivery of all medical monitoring activities of a clinical trial and in the provision of medical oversight for clinical trials.
- Coordination of safety and medical monitoring related documents and processes (e.g. Trial Oversight Committee [TOC] charter and TOC meeting/committee process, Adjudication Committee [AC] charter and AC meeting/committee process, Medical Monitoring Plan and associated documents/trackers, Data and Safety Monitoring Board [DSMB] charter and DSMB meeting/committee process)
- To monitor the pharmacovigilance (PV) requirements and activities of a clinical trial in close collaboration with the Physicians and the ATL PV team.
- Review and input into PV related documents (e.g. Safety Management Plan [SMP], Development Safety Update Report [DSUR], Risk Management Plan [RMP], etc.).
- Act as a liaison between Clinical team and ATL PV team on processing and tracking of safety events, Serious Adverse Events reports, narratives, etc., during conduct of clinical trials.
- Act as a liaison between Clinical team and ATL PV team on completion and review of PV specific regulatory documents during conduct of clinical trials.
- Active involvement (contribution, preparation, participation) in trial related meetings where PV/Medical Monitors input is required regarding subject safety and/or product related safety events, e.g. Blinded Data Review Meeting, Investigator meetings, Kick-Off Meetings, Bid Defence Meetings, etc.

Knowledge, Experience & Skills Required

- Relevant degree in life sciences or experience as a medical documentation assistant or similar
- Experience working in the pharmaceutical industry as Clinical Research Associate or equivalent
- Knowledge and understanding of ICH and Good Clinical Practice with all applicable legislations
- Knowledge of regulatory and safety/medical monitoring requirements according to current legislation

If you are interested in this role a job statement for this role is available on request.

Please send all applications to:
careers@allergytherapeutics.com

Allergy Therapeutics