Associate Director, Biostatistics Oncology

Cambridge, UK

Apply


The individual lead for the statistical strategy of one or more project (i.e. compound in a targeted indication) in Ipsen development portfolio. Responsible for the discussion and implementation of rigorous, informative and when appropriate, innovative study designs, statistical models, and analysis methodologies that optimally address the research objectives by establishing the efficacy and safety of the compound. Therapeutic area supported by this position is Oncology.

Responsible for designing, implementing and reporting in a quality, timely and accurate manner, the statistical processes in clinical trials, applying state of the art concepts and tools to the interpretation of clinical trial data so that the evaluation of such data will withstand interrogation and examination by Regulatory bodies. Oversees external vendors for outsourced activities and is responsible for the corresponding deliverables (quality, budget and timelines). Helps to introduce and develop patterns of work within the clinical research group to support and enhance the delivery of clinical development objectives and achievement of clinical excellence by encouraging a team-based approach.

Responsibilities will include, but are not limited to, the following:

Related to Study Activities

- Take responsibility as a statistical adviser to global project teams and clinical study teams for appropriate project development and make contributions to the statistical work for other projects as required.

- Ensure that, in conjunction with the Early/Medical Development Director, and other groups (e.g. Pharmacokinetics) clinical development plans have a high quality, timely and robust statistical input.

- Ensure that clinical study protocols are developed with statistical input as early as possible, and that statistical review and approval of other relevant study documents (e.g. Data handling plan, Randomisation plan, SAP and TLF Shell, Clinical Study report), is conducted to high quality, robust, rigorous, objective standards.

- Lead project and study level activities with support from external vendors’ statisticians.

- Provide statistical input for Selection and evaluation of external vendors and take responsibility for ensuring that the CRO statistical deliverables meet project specifications, and that they are produced to defined quality, content and timetable standards, and to liaise with the Purchasing Manager, to facilitate the achievement of timely, relevant, robust contracts and schedules of works.

- Ensure that the Clinical Development Department has the functional specifications, quality standards and statistical input to the CRO evaluation and management process in a time frame and in accordance with clinical study team outsourcing strategy.

- Co-ordinate the clinical research components of regulatory activities with respect to statistical methods, results and evaluation in such a way as to eliminate the chances of unsuccessful regulatory submissions. Provide the written and verbal elements of regulatory submissions around the world.
• Plan, schedule and track all statistical activities, to ensure high quality, timely and accurate completion of statistical deliverables.

• Present statistical methods used in clinical studies to Regulatory bodies when required: this includes the FDA and EMEA as well as national bodies as appropriate.

• Manage the Statistical input to the regulatory review process, addressing Regulatory Bodies questions in a timely technically sound and clearly presented manner.

• Work closely with Data Management staff, within the Ipsen Group to ensure the timely availability of integrated quality databases to support ISS and ISE and the regulatory review process.

• Be responsible in conjunction with other Principal Clinical Biostatisticians/Associate Directors for increasing the awareness of clinical research staff in R&D groups in all Ipsen companies, of the importance of maintaining statistical rigour in the clinical research processes.

• Develop Statistical processes within the Ipsen Group by working with other statistician colleagues (i.e. Modelling and Simulation).

• Develop, implement or advise on appropriate new statistical developments by keeping abreast of current issues and developments in statistical theory and application.

• Maintain a good network of contacts with outside bodies relevant to clinical statistics, both within the EU and North America.

• Any other activity which may be reasonably required from time to time.

• Complete all the above activities within the framework and in compliance with R&D SOPs and other documentation in force within the Ipsen Group.

**Processes and Recommendations**

• Lead implementation of working organization and procedures and identify any needs for improvement.

• Perform new technologies intelligence and adapt to them as appropriate.

• Participate in due diligence activities and risk assessments for in-licensing agreements and new partner relationships.

• Complies with all laws, regulations and policies that govern the conduct of Ipsen U.S. staff

**Education**

Life Science and/or Information Technology graduate

**Experience**

Several years of experience in a similar position. Experience of successful involvement in submission processes. Good experience of participating in selection and management of external vendors, ideally applied in Oncology.

**Core Competencies**

• Advanced knowledge of Statistics applied to clinical studies

• High knowledge of international standards (ICH, GCP, CDISC...) and regulations related to clinical studies

• High level of expertise in the use of the statistical software (at least SAS)

• High level of expertise of oversight and management of external vendors
• Ability to work with minimal supervision as well as in a team environment
• Strong organizational and presentation skills
• Strong relationship, teambuilding, customer-focused orientation coupled with the ability to deliver results and meet or exceed agreed-upon objectives and timeframes:
• Personal flexibility and a proactive orientation;
• Ability to handle multiple priorities.
• Ability to work under time and resource constraints.
• Commitment to excellence and high standards.

IPSEN is an equal opportunity employer that strictly prohibits unlawful discrimination. We recruit, employ, train, compensate, and promote without regard to an individual’s race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, mental/physical disability, medical condition, marital status, veteran status, or any other characteristic protected by law.

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