

At Astellas, we believe that nurturing exceptional relationships with our employees delivers exceptional business results.

Everyone at Astellas has a responsibility for creating a brighter future for patients around the world. From the first moment, Astellas will inspire you to put this ethos into practice – with a positive, agile company culture and with well-defined ethical principles, values, and systems.

Everything we do is led by our company values of integrity, being patient centric, taking ownership, delivering results, and communicating openly. These values are essential to Astellas' relationship with its employees and now is an exciting time to join us as we continue to evolve as a cutting-edge, value driven life sciences innovator.

Position: Statistical Science Lead and Clinical Biometrics Site Head, China

Department: Clinical Biometrics

Line Manager: Head, Clinical Biometrics

Location: Beijing/ Shanghai

Purpose and Scope

As a very senior statistician, the primary purpose of the Statistical Science Lead and Clinical Biometrics Site Head, China is to provide regional strategic statistical leadership across projects and have a major influence on the technical capabilities of the department. With an exceptional knowledge of the scientific area of responsibility, the position is expected to ask critical scientific questions and critique devised hypotheses, designs and results interpretation

The position will support Senior management with decision making at the asset and portfolio level, identifying gaps in knowledge, tools and internal skills, or contributing to Shared Goals (SG) and long-term strategic plans. The position receives for resolution unique, far-reaching, and previously unresolved problems.

The position works independently and involves the right level of participants as needed (cross functional peers and Sr management) within or outside R&D. The position represents Astellas in interfaces with the regional regulatory agency, chair sessions in international statistics meetings, participate in industry-wide technical discussions and represent Astellas in professional societies.

Responsibilities and Accountabilities

The position directs Astellas statistical strategy, creates and organizes new areas of methodological research and is accountable to provide best in class data science support to Astellas drug development programs

- Advises project teams and statistical leads on challenging statistical design, analysis and decision-making issues.
- Performs/supervises modeling and simulations, leverages external experts to provide input to clinical development issues
- Provides oversight on statistical matters for meetings with regulatory authorities, key opinion leaders and similar experts
- Reviews key project level documents
- Participates in due diligence activities, reviews data and advises company
- Presents and defends complex statistical solutions to internal governance committees, key stakeholders, or regulatory bodies in a compelling and impactful way
- Develops and implements best in class standards, processes, and SOPs in statistics
- Institutes best practice with regards to planning, execution, interpretation, publication, communication and regulatory/HTA submission of assets
- Writes statistical position papers
- Stays at the cutting edge of methodology development in statistics, regulatory guidelines, and industry trends in drug development, particularly with respect to the Primary Focus of interest, and signals relevant developments in a timely manner for the company.
- Challenges and influences peers and senior managers inside and outside of Quantitative Sciences and Evidence Generation on best practice in their area of competence

Personal development / Collaboration

- Coaches and supports statistical leads in providing best in class data science support to Astellas drug development programs.

- As a leader of external industry or professional organizations, the position develops and maintains relationships with leading academic institutions and key statistical opinion leaders and actively participates in professional association activities to support the branding of Astellas
- Demonstrates an in-depth understanding of Astellas' priorities, and uses the position to advance Astellas' mission through high quality statistical work
- Is exceptionally effective in ensuring that Astellas stays at the forefront of recruitment, training, professional development and retention of statistical personnel.
- Serves as a functional site head for Clinical Biometrics and coordinate local activities

Required Qualifications

- PhD or M.S in Biostatistics, Statistics or related scientific field
- 12+ years (15+ years for MS) of experience in applying statistical methods in biomedical research, Pharma, CRO, Academia or Healthcare industry or in providing statistical direction in these areas
- Advanced and broad knowledge of statistical methods, along with understanding of industry practices related to the statistical analysis of clinical data
- Knowledge and skills in SAS required, knowledge of R preferred.
- Experience working in an international environment and in a matrix environment.
- Broad experience in multiple indications, has supported multiple global submission and drug development programs at different stages.
- Record of publications in clinical trials or methodological research in highly regarded peer review journals, or invited speaking engagements,
- Understand Real World Evidence, omics, digital endpoints and Machine Learning