Those who join MedImmune feel a sense of ownership about their future. They thrive with a recognised leader in the biotechnology industry and the wholly-owned subsidiary of AstraZeneca plc. Here, you will join passionate professionals who advance science, technology and medicine to develop products designed to help people live better lives. You will excel in an environment characterised by respect, integrity and growth opportunities... that encourages both individual contribution and collaborative entrepreneurial thinking. Our products and/or product candidates are designed to address areas of need in infection, oncology, respiratory disease and inflammation, cardiovascular/metabolic disease and neuroscience. Explore a MedImmune career as we strive to better more lives, more often, around the world.

Within our Clinical Development team, we are recruiting for an experienced Biostatistician either on Senior Principal Statistician or Science Associate Director level. The role is office based in our Cambridge, UK location.
For the Senior Principal Statistician job description, major duties and responsibilities are as follows:

Job Description:
Senior Principal Statisticians provide highly experienced strategic input, statistical expertise, and leadership to project teams in the design and interpretation of clinical studies and clinical development programs in support of the Global Product Statistician (GPS). Senior Principal Statisticians may be a newly appointed GPS who is developing into the full role or may lead a strategic capability or business area improvement.

Major Duties and Responsibilities:
Senior Principal Statisticians are expected to complete these tasks with minimal supervision, appropriately and pro-actively consulting with key stakeholders (eg, GPS) and line management where needed to ensure a successful outcome to agreed time, cost and quality.

- Provide statistical leadership in support of the Global Product Statistician (GPS), be a newly appointed GPS, or lead strategic capability or business area improvements with minimal supervision
- Serve as primary author for statistical sections of protocol concept sheets (PCS), protocols, clinical development plans (CDP), and integrated product development plans (iPDP)
- Perform statistical analyses and create statistical text for clinical publications and other communications
- Provide direction and statistical oversight to outsourcing partners/providers regarding requirements and standards for study-level work, holding partners/providers accountable for the quality of their deliverables
- Define and lead analysis of relevant internal and external information to inform design decisions
- Provide statistical support and leadership to clinical trial teams (CTT), clinical sub-teams (CST) and product development teams (PDT) on the development of Target Product Profile and Target Product Claims (TPP/TPC), Benefit, Risk, Value and Uncertainty (BRV(U)), clinical development plans (CDP), and regulatory strategy
- Lead development of components of regulatory submissions (eg, briefing documents, response to FDA requests, BLA/NDA, and sBLA/sNDA) and may represent MedImmune/AZ Statistics to Health Authorities (eg, Pre-IND and End of Phase II meetings)
- May provide highly experienced expert statistical leadership to the development of the capability area and to PDTs, promoting good statistical practice
- May represent the company's position in their contacts with external experts
- May also participate in providing statistical support/strategy for post-marketing/Medical Scientific Affairs activities
- Requires juggling multiple projects with varying priorities. Requires ability to recognize issues that may critically affect statistical analyses and to relay that information to appropriate level of management
- Minimal supervision, appropriately and pro-actively consulting with key stakeholders (eg, GPS) and line management where needed to ensure a successful outcome to agreed time, cost and quality

For the Science Associate Director the job description, major duties and responsibilities are as follows:

Job Description:
Science Associate Director provides statistical leadership in support of a compound(s)/product(s) within a Therapeutic Area (TA). This includes guidance on statistical methods, appropriate study design and interpretation of results; strategic input into clinical development planning; and management of Analysis and Reporting (A&R) deliverables.

Major Duties and Responsibilities:

- Function as a Global Product Statistician (GPS) by providing comprehensive statistical leadership for a compound(s)/product(s) within a Therapeutic Area (TA) and leading the statistical thinking for all aspects of the development process including definition of the target product profile/claim, formulation of go/no-go/futility criteria, evaluation of benefit/risk profile, and development of associated regulatory strategy. Responsible for statistical guidance/oversight to study-level statisticians.
- Demonstrate knowledge regarding disease(s) under study, potential mechanism(s) of action and approval pathways/histories of other current/past drugs and collaborate effectively with Clinical Research colleagues by driving statistical thinking, proper data interpretation and disciplined exploratory data analysis.

- Responsible for statistical sections of Protocol Concept Sheet (PCS), study protocols, Clinical Development Plans (CDPs), and integrated Product Development Plans (iPDPs).
- Lead development of components of regulatory submissions (eg, FDA briefing documents, response to FDA requests) and represent MedImmune/AZ Statistics to Health Authorities (eg, Pre-IND and EOP2 meetings). This will include defining and leading the analysis of relevant internal and external information to inform design decisions.
- Responsible for statistical aspects of internal governance reviews; Provide statistical guidance/oversight to study-level statisticians. May also participate in providing statistical support/strategy for post-marketing/Medical Scientific Affairs activities
- Authoring or overseeing authorship of Statistical Analysis Plans (SAPs); Authoring or overseeing authorship of Statistical Programming Plans (SPPs) as well as statistical content and data interpretation for Clinical Study Reports (CSRs) and publications or presentations.
- Effectively negotiate timelines or competing company priorities among a variety of stakeholders and Manage A&R work on the product including deliverables provided by internal resources and outsourcing partners/providers.

Educational Requirements

MS or PhD in statistics or other related field with high statistical content

Special Skills and Abilities for BOTH Senior Principal Statistician and Science Associate Director :

- Comprehensive knowledge of statistical methods and applications in study design and analysis.
- Ability to learn and apply novel statisticians in trial designs when applicable.
- Ability to communicate with clarity and influence.
- Knowledge of ICH/EMEA/FDA guidelines.
- Demonstrated ability to serve effectively as a delivery team leader.
- Ability to coachand mentor project statisticians.
- Demonstrated ability to effectively collaborate and influence throughout multiple levels of the organization.
- Working knowledge about respiratory clinical trials is a plus.

Additional Special Skills and Abilities for the level of Science Associate Director

- Ability to challenge (in good faith) the broader clinical organization to drive organizational thinking and change.
- Ability to defend statistical methods or development strategy under senior level cross functional peer review.
- Ability to lead more than one compound's development concurrently.

To be considered for this exciting opportunity, please complete the full application on our website at your earliest convenience – it is the only way that our Recruiter and Hiring Manager can know that you feel well qualified for this opportunity. If you know someone who would be a great fit, please share this posting with them.

MedImmune is an equal opportunity employer. MedImmune will consider all qualified applicants for employment without discrimination on grounds of disability, sex or sexual orientation, pregnancy or maternity leave status, race or national or ethnic origin, age, religion or belief, gender identity or re-assignment, marital or civil partnership status, protected veteran status (if applicable) or any other characteristic protected by law. MedImmune only employs individuals with the right to work in the country/ies where the role is advertised.