EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role description

Job title	Biostatistician Specialist
Job family	Core
Job sub-family	Evidence generation
Entry grade	AD06
Role summary	Provide biostatistical advice in the delivery of evidence to support benefit-risk decision-making on the development, authorisation and use of medicines.
Standard role duties & responsibilities	Perform duties reserved only for the Temporary Agent contractual category. Support EMA scientific committees and working parties in methodological aspects that contribute to scientifically sound and efficient drug development; Contribute to the development and coordination of scientific guidelines on the design and analysis of clinical trials; Develop training materials for the European Union Regulatory Network on assigned subjects; Liaise with the academic community, research organisations and learned societies to foster the development, testing and utilisation of innovative methods for the design and analysis of clinical trials; Advise companies developing medicines on the design, data collection, conduct, analysis and interpretation of clinical trials; Understand the data and evidence needs, and implement methods for data collection and analysis supporting evidence-based decision making, through interactions with national competent authorities and members of EMA scientific committees; Contribute to the ongoing programmes as a leader, coordinator or subject matter expert.
Role specific duties & responsibilities	The specific tasks of an individual job holder, linked to this role description, are further detailed and referenced in: activities of the organisational entity within which the job holder carries out those tasks;

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	the set of annual performance and development objectives, which are established together with the reporting officer; the requirement to comply with SOPs, WINs, confidentiality undertaking and other documentation relevant to the role and its scope. These will be agreed upon with the reporting officer upon assuming duties.
Managing resources	Plan most daily work details within given priorities. May have a direct supervision of one or more people performing related work. Work may include a degree of planning and coordination, including small projects.
Communication and professional contacts	Required to regularly communicate (verbally and in writing) information, which requires careful explanation and interpretation, taking into account what to communicate and how best to convey the information. Writing and creating information that is specialist, sensitive, confidential, legal and/or regulatory in nature. Regular professional contacts with others inside and/or outside the Agency on functional matters. Solicits/gives information, provides advice/guidance and should use initiative. A likely requirement is to influence others' thinking and negotiate with various parties within own job responsibilities. Normally connected to the Agency's core business or a project. In particular, a Biostatistician Specialist will: Present on behalf of the Agency externally on biostatistical and methodological topics of importance to the Agency and Network; Represent the Agency and wider Network on external scientific groups.
Essential requirements Education Experience Skills & knowledge Certificates	**Education** A level of education which corresponds to completed university studies of at least three years attested by a diploma; *Field of study* Mathematics, statistics, epidemiology, pharmacy, medicine, or related scientific subjects. **Experience** 3 years from the time when a university degree was awarded on completion of a minimum of three years of study; Proven experience in at least one of the following: designing and conducting clinical trials including operational work in protocol development, trial conduct and data analysis, interpretation and reporting; managing, transforming and analysing clinical trial data, with practical use of statistical software like SAS or R; developing and delivering training on methodology for clinical trials. In working in a multidisciplinary team and in a multicultural environment.

	Skills & knowledge n/a **Certificates** n/a
Nice to have Education Experience Skills & knowledge Certificates	**Education** Completed PhD or master's degree in mathematics, statistics or epidemiology. **Experience** In working in a regulatory environment related to the authorisation of trial conduct, e.g. in institutional review boards, evaluation of medicines or interacting with regulatory agencies. In coordinating research projects. In developing and delivering training on methodology for observational data. In designing and conducting pharmacoepidemiological studies. **Skills & knowledge** n/a **Certificates** n/a

Category	Competency	Proficiency level
Role competencies	n/a	n/a
	n/a	n/a
Sub-family competencies	n/a	n/a
	Biostatistics	Intermediate
	Applied knowledge management	Intermediate
Grade competencies	Adaptability and agility	Intermediate
	Analysing and problem solving	Intermediate
	Prioritising and organising	Intermediate
Core competencies	Ethics and integrity	Intermediate
	Team collaboration	Intermediate
	Customer centricity	Intermediate

	Results orientation	Intermediate
	Communication	Intermediate
	Cross-cultural sensitivity	Intermediate
	Continuous learning and self-development	Intermediate