



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role description

Job title	Clinical Data Publication Assistant
Job family	Corporate Functions & Administration
Job sub-family	Support Function
Entry grade	FGIII
Role summary	Responsible for the process of management of Clinical Data Publication procedures as per the assigned portfolio and interacting with stakeholders, as appropriate. Support to other Agency transparency measures as appropriate.
Standard role duties & responsibilities	The duties of the role are performed under the supervision, including guidance and support, of temporary staff. Accountable for transparency procedures and the process of management of Clinical Data Publication procedures as per the assigned portfolio according EMA processes and in line with Policy 0070 on the proactive publication of clinical data; Responsible for entering data accurately in the relevant workflow tool and tracking table and for the provision of data for reporting purposes; Ensure that all steps of the process are handled in a timely manner and according to policy criteria; Responsible for publishing updates on the relevant intranet pages; Support the management of the EMA publication tool including delivering training within the team, answering queries from users and liaising with IT and the software provider; Responsible for the preparation of the expected list of documents for publication, and subsequent validation of packages received; Liaise with the document specialist regarding the assessment of the proposed and final packages of documents received for publication on the CDP Portal; Ensure documents have been correctly redacted/anonymised according to the agreed methodology in the anonymisation report; Support publication of the Final Redacted Document Package;

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	Accountable for the correct filing in the EMA document management system; Answer Requests for Information (RFI) in line with the relevant SOP.
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; 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 with the reporting officer upon assuming duties.
Managing resources	No management or supervision of resources.
Communication and professional contacts	Required to receive and convey information, orally and/or in writing, of a routine/standard nature; receive, understand and transfer factual information without any modification. e.g. following SOPs, WINs, established rules, policies and processes; formulating responses to simple enquiries; drafting simple material, letters, minutes, reports or presentations with clearly defined exchanges of information. Standard professional contacts related to normal day-to-day working relations within own job responsibilities. Professional contact limited to the exchange of information requiring courtesy and effectiveness in dealing with others. This may include soliciting and sharing information amongst peers. Contacts with colleagues in roles of higher responsibility will usually be associated to administrative tasks. In particular, a Clinical Data Publication Assistant will: Act as primary contact with all stakeholders, requesters and any third parties involved in the CDP process, prepare all correspondence, flag any amendments required, and provide guidance.
Essential requirements Education Experience Skills & knowledge Certificates	Education A level of post-secondary education attested by a diploma, or a level of secondary education attested by a diploma giving access to post-secondary education, and appropriate professional experience of at least three years; <i>Field of study:</i> n/a Experience Up to 6 years of full time relevant professional experience; In document management. Skills & knowledge

	Understanding of the regulatory framework that applies to the work of the Documents Access and publication Department; Understanding of the policy (policy 0070) that applies to the work of the Clinical Data Publication team; Knowledge of core administrative activities (e.g. records management, meeting management). Certificates n/a
Nice to have Education Experience Skills & knowledge Certificates	Education n/a Experience In working as part of a multinational team. Skills & knowledge Attention to details and the ability to adhere to legal timelines. Certificates n/a

Category	Competency	Proficiency level
Role competencies	n/a	n/a
	n/a	n/a
Sub-family competencies	Administrative excellence	Basic
	Corporate communication	Basic
	Event and meeting management	Basic
	Applied knowledge	Basic
Grade competencies	Adaptability and agility	Basic
	Coping with pressures and setbacks	Intermediate
	Analysing and problem solving	Intermediate
Core competencies	Ethics and integrity	Basic
	Team collaboration	Intermediate
	Customer centricity	Basic

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