EMA/292019/2020

Records of data processing activity (public) in internal audit and consultancy

1.	Last update of this record, version number:	25 June 2020, version 1
2.	Reference number:	AUD1
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Internal Audit Contact: AF-AUD@ema.europa.eu
4.	Name and contact details of DPO:	dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	N/A
6.	Name and contact details of processor (where applicable)	Data processing is primarily carried out by AF-AUD. Auditors and/or experts may be insourced for specific engagements. When such insourcing occurs, the name and contact details of the data processor involved in particular engagements are always notified to the data subjects.
7.	Purpose of the processing	Processing is necessary to complete audit process or consultancy engagement. Throughout the audit process, auditors may perform reviews, interviews, data analysis, risk assessment, and other relevant work to fulfil the audit objectives. In this context auditors, and audit contractors (processors) may come across private data.

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8.	Description of categories of persons whose data EMA processes and list of data categories	The following categories of data subjects are subject to this processing operation: • Individuals dealing with EMA's contracts and individual contractors, Ema staff members, delegates, stakeholders; The following categories of personal data are collected for this processing operation: • first name, last name, title, address, e-mail address, telephone, CVs •Background data contained in meetings minutes, transactions in information systems, operational instructions or other types of data specific to the engagement accessed through data analytics tools and methods; • Performance monitoring reports • Correspondence, e-mails, etc. For some contracts: • Data related to tenderers specific capabilities such as legal and regulatory capacity, financial and economic capacity, technical and professional capacity.
9.	Time limit for keeping the data	AF-AUD only keeps your personal data for the time necessary to fulfil the purpose of collection (or further processing for archiving purpose) in accordance with the legal and policy framework set out in the EU DPR, the Agency's policy on records management, the Agency's Business Classification Scheme and retention periods. Following such framework, draft and preparatory work are eliminated 10 years after closure of applicable audit processes (including any follow-up). At the end of the administrative retention period, the files related to the internal audit activity (including personal data) are transferred to the historical archives of the European Medicines Agency (in the case of audit reports) or destroyed (in the case of supporting documents, e.g. audit working papers). Improvement Action Plans and Final Reports are stored permanently.
10.	Recipients of the data	Internal Audit and insourced expert contractor (TBD) The output of internal consultancy and audit engagements is a report distributed to the Agency's: • Executive Director, • consultancy Client(s), • Auditee(s), • All Managers, and • Integrated Quality Management Coordinators (IQM Cos). Upon request, copies of final engagement reports can be shared with the European Court of Auditors, the Internal Audit Service of the European Commission or OLAF in exceptional cases where fraud is suspected. However, the personal data that AF-AUD may collect will not be given to any third party, except to the extent and for the purpose AF-AUD may be required to do so by law or upon the Executive Director's decision. In compliance with the applicable Agency's legislative and policy framework and following suitable

		redaction, any audit report may be subject to public requests for access to document when all its actions are fully implemented.
11.	Are there any transfers of personal data to third countries or international organisations?	Data will not be transferred.
12.	General description of security measures, where possible.	The Agency has appropriate technical and organisational measures in place, including organisational policies, to safeguard the security of personal data and ensure the confidentiality, integrity and availability of the relevant systems, services and the personal data processed within them. In particular: • Paper copies are stored in locked cabinets. • Electronic copies are stored and processed only under strict security framework policy;
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	The privacy statement is made available to data subjects internally: https://docs.eudra.org/webtop/drl/objectId/090142b28482b8bd