



EMA/431511/2019

Record of data processing activity for EMA Experts database and Handling of Declarations of Interests and CVs of scientific committees' members and experts (public)

1.	Last update of this record, version number:	23 July 2021, version 2
2.	Reference number:	H4
3.	Name and contact details of controller:	Controller: European Medicines Agency (EMA) Internally: Head of Medicines Division, EMA Contact: ExpertsDB@ema.europa.eu
4.	Name and contact details of Data Protection Officer (DPO):	Contact: 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)	N/A
7.	Purpose of the processing	To list all scientific committees' members and experts involved in EMA activities with their expertise, declaration of interest (DoI) and curriculum vitae (CV). To ensure the integrity of decision-making processes at the EMA, in particular by fulfilling the legal obligation to ensure that EMA is a transparent and open EU institution and that scientific committee members and experts involved in EMA



		<p>activities have no financial or other interests in the pharmaceutical industry that could affect their impartiality.</p> <p>Both in line with Article 15(1) TFEU, Articles 62 (2) and 63 of Regulation 726/2004, the EMA's policy 0044 on handling of competing interests of scientific committees' members and experts and the EMA's Code of Conduct.</p> <p>Experts are nominated for involvement in EMA activities and included in the EMA Experts database. Experts are listed with their DoI and CV on the EMA website for transparency. DoIs are evaluated to determine if experts can participate in an EMA activity or not and if restrictions are applicable to their involvement.</p>
8.	Description of categories of persons whose data EMA processes and list of data categories	<p>In the Experts database, the EMA processes the following data on every scientific committee member and expert involved in an activity of the Agency in the context of the authorisation, supervision and maintenance of medicinal products for human and veterinary use, including meeting attendance, scientific assessment and guidance development, as well as participation in inspections.</p> <p>Contact details – extracted from ECD [kept centrally, accessible to EMA staff and NCA Experts database co-ordinators, accessible to the public on request]</p> <ul style="list-style-type: none"> • Name • Nationality • Organisation/Company name and professional address • Business telephone number, fax number and e-mail <p>Expertise – nomination form [kept centrally, accessible to EMA staff and NCA Experts database co-ordinators, accessible to the public on request]</p> <ul style="list-style-type: none"> • Nominating authority • Qualifications – degrees, diplomas and professional affiliations • Present position and time spent in current assignment • General category of activities • Specific functional expertise • Availability • Language knowledge • Expertise in quality • Expertise in pre-clinical

		<ul style="list-style-type: none"> • Expertise in clinical • Expertise in target species • Expertise in pharmacovigilance and risk management • Expertise in control/inspections GMP/GLP/GCP • Expertise in patient/consumer representation <p>Declaration of interest [kept centrally and published on the EMA website]</p> <p><u>Direct interests</u></p> <ul style="list-style-type: none"> • employment in pharmaceutical companies • consultancy to pharmaceutical companies • strategic advisory role for pharmaceutical companies • financial interest in pharmaceutical companies • involvement of the expert in the repurposing of a medicinal product <p><u>Indirect interests</u></p> <ul style="list-style-type: none"> • principal investigator in company instigated clinical trials • investigator in company instigated clinical trials • involvement of the expert's organisation in the repurposing of a medicinal product • grants or funding from pharmaceutical companies to the organisation or institution to which the expert belongs • close family member direct interests in pharmaceutical companies <p><u>For members and alternates of the Committee for Advanced Therapies</u></p> <ul style="list-style-type: none"> • direct and indirect interests in the biotechnology sector and the medical device sector <p><u>Other interests or facts</u> (optional)</p> <p><u>Interest level</u></p> <p>Calculated based on interests declared and time frame of the interests, value 1 to 3</p> <p><u>Date of DoI</u></p> <p>To calculate status: green (DoI less than 1 year old) or amber (DoI older than 1 year) [status only kept centrally]</p>
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9.	Time limit for keeping the data	<p>Expertise (nomination forms), DoIs and CVs of scientific committees' members and experts are kept for 15 years after the experts cease their activities with the EMA, i.e. following a request from the nominating authority to remove the expert from the Experts database or if an expert has not updated his/her DoI in the last 3 years.</p> <p>The 15 year retention period is included in the EMA's business classification scheme.</p> <p>Only the current DoI, if less than 1 year old, and the current CV are published on the EMA website. Scientific committees' members and experts with a DoI older than 1 year are removed from the website.</p>
10.	Recipients of the data	<p>All EMA staff members have read-only access to the Experts database via the EMA intranet (expertise, DoIs and CVs). Data from the Experts database is accessible to the public on request, at the Agency's offices.</p> <p>EMA Experts database co-ordinators in H-Division and V-Division have write access to the Experts database to create and validate requests for new experts, to edit contact details of existing experts and NCA contact points and to move experts to the deleted experts area within the database.</p>

		<p>EMA IT staff members have administrator rights to the Experts database.</p> <p>NCA Experts database co-ordinators in the member states have write access to the Experts database for experts nominated by their authority to submit a request to create a new expert, to change the expertise of an existing expert and to delete an existing expert.</p> <p>DoIs, CVs and interest levels of scientific committees' members and experts are published on the EMA website for experts with a DoI less than 1 year old.</p>
11.	Are there any transfers of personal data to third countries or international organisations?	N/A
12.	General description of security measures, where possible.	<p>The Experts database is an electronic system with restricted access and secured by standard EMA security practices in line with EMA's Security policy 0076.</p> <p>The Experts database is not accessible to the public. The Experts database is only accessible to EMA staff and NCA Experts database co-ordinators.</p> <p>Experts can only validate/sign electronically their own DoI by using their personal and unique username and password.</p> <p>DoIs, CVs and interest levels of scientific committees' members and experts published on the EMA website are an extract from the Experts database including only experts with a DoI less than 1 year old.</p>
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	<p>Details concerning the processing of personal data are available on the Agency's website at: https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement, where experts may find the EMA General Privacy Statement as well as the privacy statements on specific data processing operations.</p>