Verification application form

EMA/557970/2024

This application form is to be used for requesting the Agency to verify that the applicant meets the conditions set out in section 1.8 of the [Fee Regulation Working arrangements](https://www.ema.europa.eu/en/documents/other/new-fee-regulation-working-arrangements_en.pdf) for the purpose of benefiting from the fee reduction laid down in point 2 of Annex V to Regulation (EU) 2024/568.

1. Information on the applicant and the intended request for scientific advice

All fields included in the table below are required to be filled with the corresponding information. The requestor for the verification of compliance should be the same as the requestor of the planned request for scientific advice.

Please note that before submitting this verification request, the applicant may first need to (1.) register their entity in SPOR and (2.) obtain a research product identifier. The links in the table below provide guidance for applicants to the corresponding starting points.

Please note that for the subsequent submission to request scientific advice, an EMA customer account (Financial account, [EMA webpage](https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency/how-pay)) also needs to be obtained.

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|  | Applicant information  |
| Organisation name (hereinafter referred to as “your entity”)  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Organisation ID (as per [SPOR](https://spor.ema.europa.eu/omswi/#/)) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of the contact person for request  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Email of the contact person for request  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Research product identifier(s) ([RPI](https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-advice-protocol-assistance/requesting-scientific-advice-or-protocol-assistance-ema#research-product-identifier-10288)) concerned by this request  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Condition, indication, context of use or other information to specify the scope of the scientific advice that you intend to request | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| If you previously requested a verification for this RPI(s) and scope of scientific advice: provide the verification number. If not, go to section 2.  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| If compliance had been confirmed for the verification number above: Has any information in the ‘Declaration of the entity status and operation’ changed compared to the previous verification request? | [ ]  Yes, therefore I complete the section ‘Declaration of the entity status and operation’ below. [ ]  No, the information is still accurate and applicable.  |
| If compliance had been confirmed for the verification number above: Has any information in the ‘Declaration of the public and veterinary health impact’ changed compared to the previous verification request? | [ ]  Yes, therefore I complete the section ‘Declaration of the public and veterinary health impact’ below. [ ]  No, the information is still accurate and applicable.  |

1. Declaration of the entity status and operation

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|  | Applicant declaration  |
| Is your entity pursuing research in fields / areas relevant to the work of EMA? Provide references on the purpose and / or overview on activities of the entity, as links to public documents or as attachment(s).  | [ ]  Yes, and this is shown by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No  |
| Is your entity by its legal form non-profit-making, or does it have a legal or statutory obligation not to distribute profits to its shareholders, owners or members? (Applicants who are a natural person should declare “yes” if they are acting as independent researchers, without profit-making objectives for the research project concerned by the sought advice.) | [ ]  Yes [ ]  No  |
| Do you have proof that your entity by its legal form is non-profit-making? (Applicants who are a natural person should provide evidence that they are acting as independent researchers, without profit-making objectives for the research project concerned by the sought advice.) | [ ]  Yes, the corresponding document(s) as per the Annex below is / are attached to this form. [ ]  Yes, such proof was already provided in the context of the verification number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No, such proof cannot be provided because \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Has your entity undergone Legal entity validation by the European Commission ([EU Funding & Tenders Portal](https://webgate.ec.europa.eu/funding-tenders-opportunities/display/OM/Registration%2Band%2Bvalidation%2Bof%2Byour%2Borganisation#Registrationandvalidationofyourorganisation-Validationofyourorganisation)), and is this validation still valid?  | [ ]  Yes, for the Participant Identification Code ([PIC](https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-register-search)): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Organisation type as per PIC: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Start date of last EU project of this PIC: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Do you have proof of a legal or statutory obligation of your entity not to distribute profits to shareholders, owners or members? | [ ]  Yes, the corresponding document(s) as per the Annex below is / are attached to this form. [ ]  Yes, such proof was already provided in the context of the verification number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No, such proof cannot be provided because \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Does your entity have any operating agreement(s) with any private profit organisation (PPO) that could concern the PPO’s sponsorship or participation in the research project concerned by the scientific advice that you intend to request?  | [ ]  No [ ]  Yes, and they are described below |
| Is your entity owned or controlled directly or indirectly by any PPO? This includes (i) the direct or indirect holding of more than 50 % of the nominal value of the issued share capital in the applicant, or of a majority of the voting rights of the shareholders or associates of that applicant; or (ii) the direct or indirect holding, in fact or in law, of decision-making powers in the applicant or in the scientific results of the subject directly resulting from the incentivized procedure. | [ ]  No[ ]  Yes |

If applicable, description of any operating agreement with a PPO that could concern the PPO’s sponsorship or participation in the specific research project concerned by this verification:

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| Are the above-mentioned agreement(s) exclusively material transfer(s) agreements that confer to the provider less than 50% of the ownership of the results directly obtained from the research project concerned by the scientific advice that you intend to request?  | [ ]  Yes [ ]  No |

1. Declaration on public and veterinary health impact

Please attach to this application a draft of the briefing document of the scientific advice that you intend to request. Section “1. Introduction” should include information on the following questions, as applicable. You can find the briefing document under this [template link](https://www.ema.europa.eu/en/documents/template-form/chmp-protocol-assistance-scientific-advice-briefing-document-template_en.docx), on this [webpage](https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-advice-protocol-assistance/requesting-scientific-advice-or-protocol-assistance-ema). For qualification advice, the draft of the briefing book should be based on the relevant section starting p 10 of this [guidance to applicants](https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/qualification-novel-methodologies-drug-development-guidance-applicants_en.pdf) (“Draft proposed format […] in clinical drug development” / “in the non-clinical setting”), on this [webpage](https://www.ema.europa.eu/en/qualification-novel-methodologies-medicine-development).

Please note it is not expected that all fields in the following table apply to a given request. The information in the following table complements the information in the briefing book.

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|  | Applicant information  |
| Is a draft briefing document is attached?  | [ ]  Yes [ ]  No, the briefing document provided in the context of the verification number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ applies.  |
| Is the research project concerned by the scientific advice that you intend to request part of an undertaking subjected to a public-private partnership?  | [ ]  Yes, a copy of the signed agreement is attached and the identification number (e.g. Horizon grant number) is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [ ]  No  |
| Is the entire research project concerned by the scientific advice that you intend to request part of the development of a PRIME-designated medicinal product and indication?  | [ ]  Yes, PRIME number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No  |
| Which practical impact will the scientific advice that you intend to request have on the planned research and development?  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Does the research project concern a public or veterinary health priority? If no, skip the next question.  | [ ]  Yes, namely \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No |
| In which way will the advice improve the potential of the research for addressing public or veterinary health priorities?  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Does the funding obtained for the research project *exclude* to carry fees for regulatory services? | [ ]  Yes, and proof is attached [ ]  No, but the funding cannot be used to carry fees for regulatory services for the following reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Does the scientific advice that you intend to request concern a multi-national clinical trial(s), or critical-to-quality factors of a clinical trial that is fully part of the research project?  | [ ]  Yes, see in the briefing book section(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No  |
| Does the scientific advice that you intend to request concern the generation of information on proof-of-principle and medical plausibility of a medicinal product with a view to a marketing authorisation application or modification thereof?  | [ ]  Yes, and this is evidenced by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No |
| Does the scientific advice that you intend to request concern the development of tools or methodologies that will be * addressing regulatory science research needs,[[1]](#footnote-1)
* accelerating or strengthening medicines evaluation, or
* enabling to involve international researchers in the research project?
 | [ ]  Yes, tool(s) / methodologies / anticipated impact(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No |
| Is your entity in a position to implement scientific advice recommendations, e.g. does your entity hold necessary rights and has freedom to operate with respect to the research concerned by the scientific advice that you intend to request? | [ ]  Yes, because \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  No |

1. Signature

I declare that the information I provided in this form and attachments is accurate, complete and true.
I undertake to submit a new application form and declaration if required by changing circumstances that render any of the information provided above outdated.

Date and signature from (an authorised representative of) the applicant submitting this form

Send an email with this form as PDF file including the relevant attachments using the subject line
“Verification request – <some details of applicant’s choice>” to academia@ema.europa.eu

Annex

Examples of documents that different types of entities may need to provide with their request of verification of compliance as proof of their ‘Declaration of the entity status and operation’.

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| **Legal entity**  | **Description** | **Document(s) to be attached to request for verification**  |
| Higher or Secondary education establishment  | Recognised by its national education system as able to deliver diplomas recognised by the State. Can be a public body or a private entity. | Copy of an official document attesting that the entity is recognised as ‘secondary or higher education establishment’ by the national education system and is entitled to deliver diplomas recognized by the State |
| Research Organization | Entities established as non-profit organization that carry out research and/or technological development as its main objective. | Copy of an official document attesting research or technological development as the main objective of the entity AND Proof of a legal or statutory obligation not to distribute profits to shareholders or individual members. |
| Research Consortia | Non-legal entities bounded by a research collaboration agreement  | Copy of the collaboration agreement. The consortia coordinator must be affiliated with an eligible non-for-profit organization. |
| Non-governmental or civil society organisation | Organisations established as non-profit which are independent of government involvement and fund or carry out research and/or technological development. | Validated by the EC at the F&T participants database as such *or*Proof of a legal or statutory obligation not to distribute profits to shareholders or individual members |
| Private law bodies with a public service mission | Legal entity incorporated under private law NOT considered to be a public body even if owned by the State/other public bodies and/or pursuing a public service mission. | Proof of a legal or statutory obligation not to distribute profits to shareholders or individual members. |
| International organization | Intergovernmental organisation with legal personality under international public law | Copy of the relevant international treaty creating the organisation under international public law |
| Public body/ Organization | Any legal entity established as a public body by national law or an international organisation | Copy of the act, law, decree, or decision that established the entity as a public body  |

1. <https://www.ema.europa.eu/en/about-us/what-we-do/regulatory-science-research/regulatory-science-research-needs> [↑](#footnote-ref-1)