



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Explanatory Note on the Pre-submission Request Form

The European Medicines Agency has recently updated and expanded its in-house tracking system, SIAMED, to manage pre-submission requests. In order to facilitate submission and handling, a single form has been designed to cover all pre-submission requests. It aims to record only necessary administrative information. Depending on the nature of the request, Applicants may be required to fill in additional forms or append additional information.

Applicants should use this [Pre-submission request form](#), along with additional supportive documentation, for:

- Intent to submit ATMP classification request
- ATMP Classification Request
- Eligibility for European Medicines Agency Procedure (ITF)
- Intent to Submit ATMP Certification Request
- ATMP Certification Request
- Eligibility to Centralised Procedure
- Intent to Submit a MA Application
- Pre-submission Meeting Request (MAA) in addition to the [Pre-submission meeting request form](#)
- Accelerated Assessment (MAA) Request

This form should also be used for to amend ongoing pre-submission requests, namely as:

- Notification of Change (administrative request, e.g. change of Applicant and contact details)
- Withdrawal of Pre-Submission Request

To whom you should send this form:

- Requests for Eligibility to the Centralised Procedure, where the pre-submission form should be sent to CPeligibility@ema.europa.eu, together with the relevant additional justification (Annex 1 SPC and Annex 2 Justification for eligibility), as separate Word documents.
- Intent to Submit an ATMP classification and ATMP classification request: this form should be sent to AdvancedTherapies@ema.europa.eu. For the ATMP classification request, the supporting 'ATMP classification briefing information' should be included as a separate Word document using the relevant [template](#).
- Request for Regulatory Advice on Eligibility for European Medicines Agency Procedure (ITF) should be sent to ITFsecretariat@ema.europa.eu

For all other applications please submit this form electronically to h-cig2@ema.europa.eu

