11 March 2022

EMA/948330/2022/Rev1

Human Medicines Division

ATMP academic development support pilot

Application form

Guidance text is in green italics. You may print a copy of this template with the guidance text, then delete all guidance text for completion.

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| **Applicant details** |
| Organisation name: |  |
| Organization address: |  |
| Contact person name: |  |
| Contact person e-mail: |  |
| Contact person telephone: |  |
| Applicant type(select one) | ☐ Public / Not-for-profit hospitals or research organisations ☐ Higher Education Institution (HEI) ☐ Public-Private Partnerships / Consortia ☐ International Research Organisation ☐ Other. Please specify:  |
| Applicant [Participant Register Identification Code](https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/participant-register) - PIC number (if available) |  |
| **Application date** |
| Application date |  |
| **ATMP Product Type [[1]](#footnote-2)** |
| ☐ Gene Therapy Product☐ Somatic Cell Product☐ Tissue Engineered Product☐ Combined product |
| **Stage of development (select one)** |
| ☐ Non-Clinical[[2]](#footnote-3)☐ Exploratory Clinical[[3]](#footnote-4)☐ Confirmatory Clinical[[4]](#footnote-5)☐ Other. Please specify:  |

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| **Product (specify below)** |
| Name / identifier: | Click or tap here to enter text. |
| Product description:*(max. 100 words)* | Click or tap here to enter text. |
| Mode of action*(max. 100 words)* | Click or tap here to enter text. |
| Intended use/indication*(max. 100 words)* | Click or tap here to enter text. |
| EMA UPI/RPI number*(if previously assigned)* | Click or tap here to enter text. |
| PRIME status | ☐ This product has been granted eligibility to PRIME [*include PRIME number*]: ☐ This product has been denied PRIME eligibility☐ This product has not been submitted for PRIME eligibility☐ Eligibility to PRIME is currently under review  |
| Previous / ongoing contact or applications with other **EMA** schemes on this product (e.g. Scientific Advice, Qualification, ATMP classification, Paediatric, Orphan etc.) | Click or tap here to enter text. |
| Previous and/or ongoing interactions with **other regulators** on this product (e.g. National Competent Authority, third country regulator, e.g. FDA, etc.) | Click or tap here to enter text. |
| Are you or your institution involved as an expert in EMA-related activities? If so, please provide details. | If yes, provide details |
| Does the applicant own or have control over the manufacturing process / reagents / starting materials / product (e.g. via intellectual property rights, commercial agreements)? | If not, provide details |
| Main clinical study(ies) number/name and status (e.g. planned, ongoing, completed);Name and email of principal Investigator of the main study;Countries of investigational sites.  | Click or tap here to enter text. |

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| **1. Information on the product** |

1.1. Description of the active substance (including from which starting materials it comes from, when relevant)

Click or tap here to enter text.

1.2. Description of any additional substances (when applicable, e.g.: structural components such as scaffolds, matrices, biomaterials, biomolecules and/or other components, medical devices)

Click or tap here to enter text.

1.3. Description of the finished product (Qualitative & quantitative composition, mode of administration)

Click or tap here to enter text.

1.4 Description of the full manufacturing process and scale for active substance and finished product. Please indicate if GMP manufacturing is in place (or GMP-like conditions). Describe any plans to scale up or changes in the manufacturing process in the future.

Click or tap here to enter text.

This section can be replaced by the quality section of the investigational medicinal product dossier (IMPD), or equivalent.

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| **2. Applicant’s justification for unmet medical need** |

***[To be completed ONLY for products without PRIME designation.]***

Click or tap here to enter text.

[In this section, the applicant should discuss the unmet medical need and potential of the medicinal product to address this unmet medical need, and the strength of evidence available to support justifying fulfilment of an unmet medical need. The description of the strength of evidence should include a brief outline of the main available non-clinical and/or clinical evidence on which the applicant bases its claim. Specifically, the applicant should present its assumptions of potential benefit(s) and these should be plausible and where possible based on a sound understanding of the product’s pharmacology and relationship of pharmacological effects to clinical outcome.

In addition to any data on clinical efficacy or activity, a high level summary of available safety data obtained in the non-clinical and clinical setting should be included here and further discussed where appropriate in Section 3. Alternatively, a copy of the investigator’s brochure or IMPD is also acceptable.]

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| **3. Overview of development plan** |

***[To be completed ONLY for products without PRIME designation unless significantly new information is available since its PRIME designation]***

**3.1 Non-clinical data**

Click or tap here to enter text.

In addition to the above summary from Section 2, the applicant should provide a brief overview of non-clinical data. This should preferably be presented as tables and figures, with relevant comments.

This section can be replaced by the non-clinical section of the IMPD, or equivalent.

**3.2 Clinical data**

Click or tap here to enter text.

In addition to the above summary from Section 2, the applicant should present a brief description of the design of the completed/ongoing/planned study(ies), treatment(s) and patient population (numbers, relevant baseline characteristics, disease severity).

Results (if available) should be discussed with regard to their clinical relevance and biological plausibility in the proposed target population.

Known serious/treatment emerging adverse events should be summarised in a tabular format.

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| **4. Additional information you wish to share**  |
| Click or tap here to enter text. |

1. In case of doubt, submit in advance or in parallel a request for ATMP classification (https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/advanced-therapies-marketing-authorisation/advanced-therapy-classification) [↑](#footnote-ref-2)
2. First in Human study not yet started or not completed. [↑](#footnote-ref-3)
3. Exploratory clinical studies underway/completed - clinical response and safety data available from exploratory clinical studies in patients in the targeted indication. [↑](#footnote-ref-4)
4. Confirmatory clinical study underway/completed - study(ies) intended to generate substantial evidence for registration. [↑](#footnote-ref-5)