Application Form of Pre-clinical and Clinical Technical Support Request

Items	comments
Applicant Name	
Rep. Name	
Official delegation letter	
E-Mail	
Phone	
M.A.H/ Sponsor	
Manufacturer	
Covering letter	
Proof of Payment	
Technical support type	
Name of product	
Product type	☐ Recombinant DNA derived products/GMO ☐ Vaccine ☐ Plasma derived product ☐ Extract ☐ ATMP ☐ Others
Active substance	
Pharmaco-therapeutic group	
Developmental Phase	☐ Preclinical ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV
Approved indication(s)	
Manufacturer status	☐ local ☐ Imported
Rational for submission of scientific advice	☐ Laboratory testing issues ☐ Quality ☐ Non-clinical ☐ Development issues ☐ Similarity ☐ Others

Regulatory status	☐ Pre-authorization ☐ Post-authorization ☐ Submitted to registration directorate (specify at which step……..)
Required scientific advice pre-submission meeting	☐ Yes ☐ No
Value of the trial	[Describe value propositions and how the trial evidence will be used to support these]
Background information	[This section should give a comprehensive scientific overview of the product development program, providing relevant systematic information in sufficient detail, together with a critical discussion. However, it should be kept in mind that any information essential for the justification of a given question should also be sufficiently discussed in the corresponding Company's position. The proposed list of subsections is neither meant to be exhaustive nor mandatory, since the relevance or applicability of each subsection may vary depending on the scope of the advice request. In this respect, the potential direct or indirect relevance of the information covered in relation to the questions posed should be considered. Additional details can be included in study protocols, study reports, investigators' brochure provided as annexes. The use of tabulated overviews and graphs is encouraged.*]*
Disease to be treated	Outline main features of the disease and current standard therapy (referencing relevant guidelines), referring to relevant publications as well as any current unmet need(s)
Intended Indication	Please specify the proposed wording for the intended indication, posology, and any special precautions or recommendations for use of the product (including a possible risk management strategy
Description of the product	Include mode of action, chemical structure, pharmacological classification, proposed dosing regimen, route of administration and details of any additional diagnostic tests, medical devices or medical procedures that the use of the new product will incorporate
Non-clinical information	Please provide brief information on pre-clinical trials in a tabulated overview, only if these are relevant to the advice sought.
Clinical information	A tabular overview of all clinical studies (completed, ongoing and planned), should be included. Please try to include study number, protocol synopsis, location(s), trial objectives, trial design, randomisation, blinding, and

	intervention, patient population, inclusion/exclusion criteria, identified subgroups, comparators, endpoints, health-related quality of life (HRQL), duration/follow P up and methods of analyses where applicable. Briefly include outcomes of completed trials, including safety assessments. Whilst the focus should be kept on the intended indication, the development in other indications could be briefly summarised, where relevant
Other NRAs Regulatory status	[Describe the worldwide regulatory status of the product (e.g. any existing MA, or planned MAA timelines).]

Indication	**EMA**	**FDA**	**Others NRAS**
Intended indication			
Other indication #1			
Other indication #2			

Questions and Company's positions	[It is recommended that questions are phrased in a way to allow for an unambiguous understanding of the question. -The scope should be carefully considered in order to avoid too broad or too narrow questions. Questions should be ordered in the corresponding section according to the expertise (also multidisciplinary) required for the assessment, and numbered sequentially. Each question should be followed by a corresponding, separate Company's position including a comprehensive justification of the chosen approach. All key information about the topic should be sufficiently discussed, so that the Company position can function as a 'stand-alone' argument. Issues to be covered could include the following: context and proposal, other options (potentially) considered together with a critical discussion on the relative merits and drawbacks of various approaches, possible consequences and eventual measures to ameliorate these. In general, an extension of 1 to 3 pages for each Company position is recommended.

	Cross-references to the relevant parts of the briefing document or annexes can be included if additional detail is needed to support the argument.]
Attached files	
Reference /Guidelines	

Signature of the applicant:

I.1 I hereby confirm that: ☐ the information provided is complete; ☐ the attached documents contain an accurate account of the information available;
Date: **Signature:** **Print name**: