Innovation Meeting - Request Form

|  |  |
| --- | --- |
| Applicant name: |  |

Innovation Meetings (IM), organised under the remit of the Innovation and EMA Scientific Advice Office, provide a forum for early dialogue with developers of innovative products.

Their scope covers discussion on new technologies, advanced therapies, new methodologies, borderline and nanotechnology-based products.

During IMs, the Applicants may discuss the innovation brought by their product in the regulatory and technical-scientific fields.

Their objective is to facilitate informal exchange of information, anticipate the regulatory issues that the product development might encounter due to its innovative nature and provide guidance in the development process, complementing and reinforcing existing formal procedures.

The IM informal discussions are led by experts from the AIFA network whose expertise is identified in advance to respond to needs specific for each request.

The meetings are free of charge.

Prior to the IM, Applicants should fill in this form and provide a Briefing Document that introduces the product/technology/methodology and the topic(s) for discussion. This document (maximum of 30 pages) could include the following information, as applicable:

* General background information
* Description of the technology/ method
* Composition of the product and description of the manufacturing process
* Description of the non-clinical and/or clinical development
* Presentation of the topics for discussion.

Annexes can be added as needed.

Following your request, the Innovation and EMA Scientific Advice Office could request additional information or, if necessary, offer a teleconference to validate the Briefing Package and identify the most relevant issues for discussion. A date and time for the IM will be arranged.

To apply for an IM and send the documents mentioned above, please email to:

innovation.office@aifa.gov.it

Please fill in the yellow boxes:

|  |  |  |
| --- | --- | --- |
| **Applicant** | **Date of application:** |  |
| Applicant name: |  |
| Address: |  |
| Contact person: |  |
| E-mail: |  |
| Phone: |  |
| Type: | □ Pharmaceutical industry□ Small and medium-sized enterprise (SME)□ Academic institution□ Research entity □ Other - *Please specify*: |

|  |
| --- |
| **Product/technology/methodology features** *Type an 'X' in the appropriate yellow box(es)* |
| **Innovative therapies & technologies** | **Innovative development methods** |
|  | Gene therapy |  | New non-clinical method/ model |
|  | Somatic cell therapy |  | Biomarker *(e.g. -omics, assay [co-] development)* |
|  | Tissue engineering |  | Novel statistical approach *(e.g. modelling & simulation)* |
|  | Nanomedicine |  | Novel clinical trial methodology |
|  | New manufacturing technology |  | Other *- Please specify*: |
|  | New delivery system | **Other** |
|  | Other *- Please specify*: |  | Borderline medicinal product - *Please specify*: |
|  |  |  |

|  |
| --- |
| **Product/technology/development method** |
| Name/identifier: |  |
| Product/technology description:*(max. 100 words)* |  |
| Mode of action:*(max. 100 words)* |  |
| Intended use: |  |

|  |
| --- |
| To help us establish how innovative your product / technology / development method is, please indicate: |
| **Same or similar substance/technology reviewed, approved or marketed in** |
|  |
| **Type of innovation** |  | Therapeutic innovation |
|  | Scientific innovation |
|  | Technical innovation |
| **Topics to be discussed** |
| Scientific: |  |
| Regulatory: |  |
| General: |  |

|  |
| --- |
| **Preferred month(s) for the meeting** |
|  |
| **Previous/parallel contact with other Italian regulatory bodies or scientific or research institutions**  |
| **Type of activity/procedure and ID number:****Institution:****Date:****Scope:****Brief description:** |
| **Previous/parallel contact with other international regulatory agencies or scientific or research institutions**  |
| **Type of activity/procedure and ID number:****Institution:****Date:****Scope:****Brief description:** |