Request for Performance Study Pre-submission Meeting

It is recognised that interaction may be sought with the HPRA at different stages of development of an *in vitro* diagnostic medical device (IVD) and that some of the information requested on this form may not be available to all organisations seeking advice, but please provide as much detail as possible. If there is not enough space in the boxes provided, please attach any relevant documentation to this form.

1. Administrative information

|  |  |
| --- | --- |
|  | Date of request: |
|  | Organisation seeking advice:  Name  Address |
|  | Applicant’s contact details:  Contact person  Telephone  Email address |
|  | Have you had any previous interactions with the HPRA Medical Devices department relating to this IVD?  Yes HPRA reference number(s) (*if applicable):*  No |

1. About the product

|  |  |
| --- | --- |
|  | Name of the IVD: |
|  | Proposed intended use: |
|  | Class of IVD:  Class A  Class B  Class C  Class D |
|  | Is the device a companion diagnostic?  Yes Corresponding medicinal product *(if applicable):*  No |
|  | Has a classification opinion been sought from any regulatory agency or notified body?  (Please attach notification of classification opinion, if applicable.) |
|  | What is the current regulatory status of the device?  No regulatory approval worldwide  Regulatory approval outside EU (Please specify: )  CE mark for intended purpose other than proposed intended use for current research  Other: |
|  | Please list the Irish site(s) being considered for this performance study. |
|  | Has approval been sought from another competent authority for a performance study using this device? If so, please provide EUDAMED CIV ID. |
|  | Is this performance study proposed to take place in any other member states or in other sites worldwide? (Please specify, if applicable.) |
|  | Has an Irish ethics committee been approached in relation to this performance study?  Yes  No  If ‘Yes’, please provide details: |
|  | Please provide an indication of the planned timelines for this performance study. (Please note these timelines are viewed as indicative only.) |

1. Supporting Information

|  |  |
| --- | --- |
|  | Please provide a summary any pre-study testing conducted for the device under consideration. (Alternatively, please attach as a separate document and reference here.) |
|  | Please detail any specific queries you would like answered as part of this pre-submission process. (Please note that the HPRA may not be in a position to answer all queries, but will endeavour to direct you towards other sources of information, where possible.) |

1. declaration

|  |  |
| --- | --- |
| **Signed for and on behalf of <company name>.** | |
| **Signed**: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Date**: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| Position: | |
| **Please send the completed form and accompanying documentation by email to** [**devices@hpra.ie**](mailto:mdevices@hpra.ie)**.** | |