Request for Clinical Investigation Pre-submission Meeting

When completing this form, please refer, where appropriate, to the HPRA *Guide for Manufacturers and Sponsors on Clinical Investigations Carried out in Ireland* as this provides useful information and references relating to the clinical investigation process.

It is recognised that interaction may be sought with the HPRA at different stages of development of a medical device 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 medical device?[ ]  Yes HPRA Reference Number(s) (*if applicable)* [ ]  No |

1. About the product

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| --- | --- |
|  | Name of the medical device:  |
|  | Proposed intended use:  |
|  | Class of medical device:[ ]  Class I[ ]  Class IIa[ ]  Class IIb[ ]  Class III |
|  | 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 clinical investigation. |
|  | Has approval been sought from another competent authority for a clinical investigation using this device? If so, please provide EUDAMED CIV ID. |
|  | Is this clinical investigation 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 clinical investigation?[ ]  Yes[ ]  NoIf ‘Yes’, please provide details.  |
|  | Please provide an indication of the planned timelines for this clinical investigation. (Please note these timelines are viewed as indicative only.) |

1. Supporting Information

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|  | Please provide a summary of pre-clinical testing of 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

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| **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** |