Notification of a Clinical Investigation of a Medical Device under Article 82 MDR

Clinical investigations of medical devices that are not performed for any of the purposes listed in Article 62 (1) or Article 74 of the MDR require notification to the HPRA under Part 3 of the Medical Devices Regulations 2021 (S.I. 261 of 2021).

Sponsors of these clinical investigations should take note of the additional requirements for these clinical investigations as specified in Article 82(1) of the MDR and in Part 3 of the Medical Devices Regulations 2021 (S.I 261 of 2021).

Notifications will only be accepted via CESP, unless previously agreed with the HPRA. Following uploading of the documents via CESP, please email devices@hpra.ie to advise that a new clinical investigation notification has been submitted.

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| **SECTION A: Administrative Information** |
| 1 | Is this a first notification or a resubmission?[ ]  First notification[ ]  Resubmission |
| 2 | If resubmission, state previous notification date and HPRA reference number.Date      Reference no.       |
| 3 | Enter the contact details of the sponsor who is responsible for this application.Name      Address      Telephone      Email       |
| 4 | Principal investigator responsible for the conduct of the clinical investigation in Ireland:*If more than two principal investigators are involved, please attach these details as an appendix, including details and roles for members of the investigator’s team who will be directly involved in the conduct of the investigation.*(i) Name      Qualification      Address      Telephone      Email      (ii) Name      Qualification      Address      Telephone      Email       |
| 5 | Please list the clinical investigation sites in Ireland.*If more than two sites, please attach details in an appendix.**Irish site 1* Name      Address      *Irish site 2* Name      Address       |
| 6 | Is this part of a multi-site clinical investigation outside Ireland? [ ]  Yes[ ]  NoIf yes, enter details of other sites. *If more than two sites, please attach details in an appendix.**Non-Irish site 1* Name      Address      *Non-Irish site 2* Name      Address       |
| 7 | Principal clinical investigator appointed to coordinate the work in a multi-site study:Name      Qualification      Address      Telephone      Email       |
| 8 | Manufacturer's name, address, telephone and email address, including site where the manufacture of the device is taking place:Name      Address      Telephone      Email address       |
| 9 | If the sponsor is not based in a European Member State, name and contact details of legal representative:Name      Address      Telephone      Email       |
| 10 | Is this application submitted in parallel with an application for a clinical trial in accordance with EU Regulation 536/2014? [ ]  Yes[ ]  NoIf yes, please provide the clinical trial reference no.       |
| 11 | Enter proposed start and completion date of the clinical investigation:Start date      Completion date       |
| 12 | Has an Ethics Committee in Ireland provided an opinion with respect to this proposed clinical investigation? If so, please provide a copy of the opinion.[ ]  Yes[ ]  No |

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| **SECTION B: device information** |
| 1 | Name of device:       |
| 2 | Device description:       |
| 3 | What is the intended purpose of this device?       |
| 4 | Does the device incorporate a medicinal substance, including a human blood or plasma derivative?[ ]  Yes[ ]  NoHas the device been manufactured using non-viable tissue or cells of human or animal origin, or their derivatives?[ ]  Yes[ ]  No |
| 5 | Device classification[ ]  Class III[ ]  Class IIb[ ]  Class IIa[ ]  Class I |
| 6 | Will a comparator device be used during this clinical investigation?[ ]  Yes[ ]  NoIf yes, please provide details of the comparator device, including its classification and any information necessary for the identification of the comparator device. Please also confirm that this comparator device is CE marked for this intended purpose. |
| 7 | Is this device CE marked?[ ]  Yes. If yes, please complete sections C, E.1 and F.[ ]  No. If no, please complete sections D, E.2 and F. |

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| **SECTION C: Clinical Investigation information for ce marked devices** |
| 1 | Full title of clinical investigation:  |
| 2 | Short title of clinical investigation (if applicable):  |
| 3 | Title for lay persons:  |
| 4 | Name of notified body which issued the CE mark for this device:  |
| 5 | Will this device be used within its intended purpose?[ ]  Yes[ ]  NoWill the clinical investigation involve submitting participants to burdensome or invasive procedures additional to those performed under the normal conditions of use of the device?[ ]  Yes[ ]  No |
| 6 | Summary of the Clinical Investigation Plan (CIP), including the objectives of the clinical investigation, the number and gender of subjects, criteria for subject selection, whether there are any subjects under 18 years of age, design of the investigation and planned dates of commencement and completion of the clinical investigation:CIP code: CIP version number: CIP version date:  |

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| **SECTION D: Article 82 Clinical Investigation information for non-ce marked devices** |
| 1 | Full title of clinical investigation:  |
| 2 | Short title of clinical investigation (if applicable):  |
| 3 | Title for lay persons:  |
| 4 | Please describe the device development stage and a summary of the device’s development plan.  |
| 5 | Please note, in general, clinical investigations of non-CE marked medical devices, including pilot/early stage investigations, will come under the regulations of Article 62 of MDR. Please explain the rationale for this clinical investigation not falling under Article 62 of MDR. |
| 6 | Summary of clinical and preclinical testing performed on the device to date: |
| 7 | Details of novel features of the device including, where applicable, functions and principles of operation: |
| 8 | Summary of the potential benefits and risks of the device. Please include, where relevant, an identification of the hazards and hazardous situations that may result from use of the device, and an estimation and evaluation of the risks associated with these hazards and description of mitigation strategies to minimize the potential clinical effects of these hazards.  |
| 9 | Summary of the Clinical Investigation Plan (CIP):CIP code: CIP version number: CIP version date:  |
| 10 | Detailed description of monitoring activities to be employed throughout the Clinical Investigation: |

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| **SECTION E: Documentation to be attached** |
| The following list is guidance only and it is recognised that not all proposed clinical investigations require all of the following documentation. Any relevant documentation as outlined in Annex XV of the MDR (EU Regulation 2017/745) should be submitted with this notification form. The content and structure of documents submitted should be in line with relevant regulatory requirements and associated standards.  |
| 1 | **For Article 82 clinical investigations of a CE marked device, please submit:**[ ]  Clinical investigation plan (CIP) which sets out the rationale, objectives, design, methodology, monitoring, conduct, record-keeping and the method of analysis for the clinical investigationVersion number:      Date:      [ ]  Investigator’s brochure (IB) OR Instructions for use[ ]  Investigator’s brochure (IB) OR Instructions for use[ ]  A copy of the opinion of the relevant Ethics Committee on the details of the aspects covered by its opinion (if available)[ ]  Documents used to obtain informed consent[ ]  Description of arrangements for data protection and confidentiality of personal information[ ]  Proof of insurance cover or indemnification of subject in case of injury, pursuant to Article 69 of the MDR and S.I. 261 of 2021  |
| 2 | **For Article 82 clinical investigations of a non-CE marked device, please submit:**[ ]  Clinical investigation plan (CIP) which sets out the rationale, objectives, design, methodology, monitoring, conduct, record-keeping and the method of analysis for the clinical investigationVersion number:      Date:      [ ]  Investigator’s brochure (IB)[ ]  Instructions for use for the device[ ]  Details of clinical and preclinical data for the device[ ]  Details of novel features of the device[ ]  Summary of benefit/risk analysis and risk management including information regarding known or foreseeable risks, undesirable side-effects, contraindications and warnings[ ]  Monitoring plan[ ]  A copy of the opinion of the relevant Ethics Committee on the details of the aspects covered by its opinion (if available)[ ]  Documents used to obtain informed consent[ ]  Description of arrangements for data protection and confidentiality of personal information[ ]  Proof of insurance cover or indemnification of subject in case of injury, pursuant to Article 69 of the MDR and S.I. 261 of 2021 [ ]  Any other relevant documents (please list below):       |

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| **SECTION F: Declaration** |

Signed on behalf of **<sponsor>** (*if applicable)*.

I, *(please print full name in block capital letters)* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

1. Confirm that the investigational device(s) in question conform(s) to the applicable general safety and performance requirements set out in Annex I of the MDR apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects.
2. Certify that the information and documentation submitted with this notification is correct in detail and all relevant information has been supplied. Any further information requested by the competent authority will be submitted on request.
3. Undertake to keep available for the competent authority for a period of 10 years (15 years for implantable devices) after the end of the clinical investigation all the relevant documentation referred to in Annex XV of Regulation (EU) 2017/745.
4. Certify that the sponsor consents to allow the letter acknowledging notification of this clinical investigation to the HPRA to be copied to the Irish based investigators and the National Research Ethics Committee for Medical Devices (NREC-MD).
5. Certify that the sponsor consents to the HPRA contacting the NREC-MD during the course of the review if required.
6. Certify that the sponsor consents to the HPRA utilising external experts, when necessary, during the assessment of this application. (Experts used will be subject to the HPRA’s procedures for protection of confidentiality and impartiality.)

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Print name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Position:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please submit the completed form and all accompanying documents via the Common European Submission Portal at <https://cespportal.hma.eu/>.