Notification of a Performance Study for a Companion Diagnostic using left-over samples under Article 58(2) IVDR

Performance studies involving companion diagnostics using only left-over samples require notification to the HPRA under Article 58(2) of the IVDR.

Sponsors of these performance studies should note the general requirements for performance studies as specified in Article 57 and the requirements for recording and reporting of adverse events under Article 76 of the IVDR. Please refer to the HPRA [Guide to Performance Studies Conducted in Ireland](https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/guide-to-performance-studies-conducted-in-ireland.pdf?sfvrsn=5) for further details.

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 performance study 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 | Enter proposed start and completion date of the performance study.Start date      Completion date       |
| 3 | If resubmission, state previous notification date and HPRA reference number.Date      Reference no.       |
| 4 | Enter the contact details of the sponsor who is responsible for this application.Name      Address      Telephone      Email       |
| 5 | Principal investigator responsible for the conduct of the performance study 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 study.*(i) Name      Qualification      Address      Telephone      Email      (ii) Name      Qualification      Address      Telephone      Email       |
| 6 | Please list the performance study sites in Ireland.*If more than two sites, please attach details in an appendix.**Irish site 1* Name      Address      *Irish site 2* Name      Address       |
| 7 | Is this part of a multi-site performance study 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       |
| 8 | Principal investigator appointed to coordinate the work in a multi-site study:Name      Qualification      Address      Telephone      Email       |
| 9 | Manufacturer's name and address, including site where the manufacture of the device is taking place:Name      Address       |
| 10 | Manufacturer's telephone, fax number and email address:Telephone      Fax      Email       |
| 11 | If the manufacturer is not based in a European state, name and contact details of authorised representative:Name      Address      Telephone      Fax      Email       |
| 12 | Is this notification 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.:       |
| 13 | Has an ethics committee in Ireland provided an opinion with respect to this proposed performance study? If so, please provide a copy of the opinion.[ ]  Yes[ ]  No |
| 14 | Payment details (please include documentary confirmation of payment with your application, where applicable):[ ]  Cheque[ ]  Bank transfer[ ]  Bank draft[ ]  Credit on account |

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| **SECTION B: device information** |
| 1 | Name of device:       |
| 2 | Device description:       |
| 3 | 1. Is this device CE marked? If no, please proceed to Question 3c.

[ ]  Yes[ ]  No1. Which notified body issued the CE mark for this device?

     1. What is the intended purpose of this device?

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| 4 | 1. Does the device incorporate a medicinal substance, including a human blood or plasma derivative?

[ ]  Yes[ ]  No1. Has the device been manufactured using non-viable tissue or cells of human or animal origin, or their derivatives?

[ ]  Yes[ ]  No |
| 5 | Will a comparator device be used during this performance study?[ ]  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. |

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| **SECTION C: performance study information** |
| 1 | Full title of performance study:  |
| 2 | Short title of performance study (if applicable):  |
| 3 | Title for lay persons:  |
| 4 | Summary of the Performance Study Plan (PSP), including the objectives of the performance study, the number selection and source of specimens, design of the investigation and planned dates of commencement and completion of the study. |
| 5 | PSP code:  |
| 6 | PSP version number:  |
| 7 | PSP version date:  |

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| **SECTION D: Declaration** |

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

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

1. Confirm that the device(s) for performance study conform(s) to the applicable general safety and performance requirements set out in Annex I of the IVDR apart from the aspects covered by the performance study 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 performance study all the relevant documentation.
4. Certify that the sponsor consents to allow the letter acknowledging notification of this performance study to the HPRA to be copied to the Irish based investigators and the relevant Ethics Committee(s).
5. Certify that the sponsor consents to the HPRA contacting the relevant Ethics Committee(s) during the course of the review if required.

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

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

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

**Company name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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