**Tilkynningareyðublað**

**Klínískar prófanir á lækningatækjum**

Þetta eyðublað er ætlað fyrir tilkynningu um framkvæmd klínískrar prófunar á lækningatæki sem ekki hafa verið CE-merkt og lækningatæki sem hafa verið CE-merkt fyrir önnur tilætluð not en ætlunin er að rannsaka í klínískri prófun.

Senda skal útfyllt eyðublað til Lyfjastofnunar á laekningataeki@lyfjastofnun.is

Upplýsingar úr reitum sem merktir eru með bláum lit verða færðar í EUDAMED gagnagrunninn fyrir klínískar prófanir (e. *Clinical Investigation (CI)*) á lækningatækjum .

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| **1. Clinical investigation identification and status** |
| Submission type | NCA registration number (CA Reference) if applicable |
| select submission type | fill in text |
| Submission date (YYYY-MM-DD) | Eudamed identification number if applicable(CIV-YY-MM-XXXXXX) |
| select date | fill in Eudamed identification number (CIV-) |
| Has an application for clinical investigation of a **medicinal product** linked to this notification been submitted to the NCA or will it be submitted? | EudraCT number if applicable |
| select Yes / No | fill in text |
| Title of the clinical investigation | Clinical investigation plan (CIP) code |
| fill in text | fill in text |
| Version and date of the CIP |
| fill in text |

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| **2. Manufacturer** |
| Name | Contact for this Clinical investigation, name |
| fill in text | fill in text |
| Street/road | Number/house/floor |  Phone |
| fill in text | fill in text | fill in text |
| Postal code | City |  Fax |
| fill in text | fill in text | fill in text |
| State/region | Country | E- mail |
| fill in text | select country | fill in text |

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| **3. Authorised Representative within the EEA if applicable** |
| Name | Contact for this Clinical investigation, name |
| fill in text | fill in text |
| Street/road | Number/house/floor |  Phone |
| fill in text | fill in text | fill in text |
| Postal code | City |  Fax |
| fill in text | fill in text | fill in text |
| State/region | Country | E- mail |
| fill in text | select country | fill in text |

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| **4. Sponsor, according to the EN ISO 14155 definition, if other than manufacturer or authorised representative,** **if applicable:** |
| Name | Contact for this Clinical investigation, name |
| fill in text | fill in text |
| Street/road | Number/house/floor |  Phone |
| fill in text | fill in text | fill in text |
| Postal code | City |  Fax |
| fill in text | fill in text | fill in text |
| State/region | Country | E- mail |
| fill in text | select country | fill in text |

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| **5. Medical device to be investigated** |
| Name of the medical device | Model or version |
| fill in text | fill in text |
| Generic name of the medical device (if name not specified above) |  GMDN code |
| fill in text | fill in text |
|  Name used elsewhere to market same medical device | Other internationally recognized nomenclature |
| fill in text | fill in text |
| Is the medical device CE-marked for other use than intended for this CI? | Class of device |
| select Yes / No |  select class of device |
| Intended use of the medical device in the CI |
| fill in text |
| Description of the medical device |
| fill in text |
| **6. Additional information of the medical device to be investigated** |
| Is a medicinal product integrated with the medical device or shall a medicinal product act together with it? | select Yes / No |
| Does the medical device incorporate, as an integral part, a human blood derivate?  | select Yes / No |
| Have tissues of animal origin been used in the manufacturing process?  | select Yes / No |

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| **7. Comparator medical device(s) (if applicable)** |
| Manufacturer | GMDN code |
| fill in text | fill in text |
| Name of the medical device, model or version | Other nomenclature |
| fill in text | fill in text |
| Product class | select class of device |
| Is the medical device CE-marked for the intended use in this CI? | select Yes / No |
| Is a medicinal product integrated with the medical device or shall a medicinal product act together with it? | select Yes / No |

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| **8. Clinical investigation** |
| Primary objective |
| fill in text |
| Inclusion criteria | Exclusion criteria |
| fill in text | fill in text |
| Planned total number of subjects involved | Planned number of subjects in the NCA state | Planned start date of CI | Planned completion date of CI  |
| fill in text | fill in text | fill in text | fill in text |
| Planned states within EEA, Switzerland and Turkey for the CI |
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| --- | --- | --- | --- | --- | --- |
| [ ]  | Austria | [ ]  | Hungary | [ ]  | Poland |
| [ ]  | Belgium | [ ]  | Iceland | [ ]  | Portugal |
| [ ]  | Bulgaria | [ ]  | Ireland | [ ]  | Romania |
| [ ]  | Cyprus | [ ]  | Italy | [ ]  | Slovakia |
| [ ]  | Czech Republic | [ ]  | Latvia | [ ]  | Slovenia |
| [ ]  | Denmark | [ ]  | Liechtenstein | [ ]  | Spain |
| [ ]  | Estonia | [ ]  | Lithuania | [ ]  | Sweden |
| [ ]  | Finland | [ ]  | Luxembourg | [ ]  | Switzerland |
| [ ]  | France | [ ]  | Malta | [ ]  | Turkey |
| [ ]  | Germany | [ ]  | Netherlands | [ ]  | United Kingdom |
| [ ]  | Greece | [ ]  | Norway |  |  |

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| **9. Clinical investigation – Design and additional information** |
| Area of investigation |
| [ ]  Cardiology | [ ]  Surgery | [ ]  Orthopaedics | [ ]  Oncology | [ ]  Radiology | [ ]  Other |
| Secondary objective(s) |
| fill in text |
| Summary of clinical investigation plan |
| fill in text |
| Controlled study? | select Yes / No |
| If controlled | [ ]  Parallel groups  | [ ]  Cross over | [ ]  Other |
| Randomization? | select Yes / No |
| Masking [ ]  Open | [ ]  Single blinded  | [ ]  Double blinded | [ ]  Blinded evaluation |
| Gender | select Men/Women/Both |
| Subjects <18 yrs? | select Yes / No |
| If yes, which ages? | fill in text |
| Countries outside EEA, Switzerland and Turkey participating in the CI? | select Yes / No |
| If yes, which? | fill in text |

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| **10. Mandatory attachments** |
| Clinical Investigation Plan, CIP | select Yes / No |
| Investigator’s Brochure, IB | select Yes / No |
| Copy of clinical investigation insurance policy covering the participating subjects | select Yes / No |
| Subject information and consent form (in national language) | select Yes / No |
| Copy of the opinion of the Ethics Committee if available | select Yes / No |
| List of National investigations site(s), Clinical Investigator (s)  | select Yes / No |
| Qualifications of the principal investigator and one investigator per site | select Yes / No |
| Declaration of conformity with Essential Requirements | select Yes / No |
| **11. Attachments, if not included in the IB, as applicable** |
| Results of risk analysis | select Yes / No |
| List of applied standards: Standards applied in full and description of deviations from applicable harmonised European standards. | select Yes / No |
| Documentation on tissues of animal origin in the investigational device | select Yes / No |
| Documentation on human blood derivate in the investigational device | select Yes / No |
| Documentation on medicinal substances in the investigational device | select Yes / No |
| Documentation of products/drugs/substances which the device under investigation will be used together / co-act / be compared with | select Yes / No |
| Intended device labelling | select Yes / No |
| Instructions for use to subjects (in national language) or professional users | select Yes / No |
| Case Report Form (CRF) | select Yes / No |
| Evaluation forms to be filled in by subjects or staff (in national language) | select Yes / No |
| Copy of the application to the Ethics Committee | select Yes / No |

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| **12. Signature** |
| Sponsor / Manufacturer / Authorized representative (if applicable) | I hereby certify that information provided in this notification is correct and I will see to that the investigation is carried out in accordance with the Declaration of Helsinki, applicable medical device directives, national regulations, EN ISO 14155 and the attached investigation plan.I keep available upon request documentation mentioned in annex 8 of directive 93/42/EEC and/or annex 6 of directive 90/385/EEC. |
| Date and signature fill in text …………………………………………………………………………………………………………… |
| Name fill in text |
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