**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 | | | | | | | | | | |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | 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 |  |  | | | | | | | | | | | |
| **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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