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| Date (form filled or amended) | | *Click or tap here to enter the date.* |
| Form filled out by (name and e-mail) | | *Click or tap here to enter text.* |
| Coordinator at Clinical Research Institute HUCH | | *Click or tap here to enter text.* |
| Project n:o at Clinical Research Institute HUCH | | *Click or tap here to enter text.* |
| Pharma industry trial (please fill out sections A-D)  Academic trial (please fill out sections A-E) | | |
|  | | |
| **A** | **STUDY INFORMATION** | |
| **A1** | EU clinical trial number | *Click or tap here to enter text.* |
| **A2** | Protocol number / study sponsor code | *Click or tap here to enter text.* |
| **A3** | Protocol full title | *Click or tap here to enter text.* |
| **A4** | Sponsor | *Click or tap here to enter text.* |
| **A5** | HUS study site | *Click or tap here to enter text.* |
| **A6** | Coordinating Investigator at HUS | *Click or tap here to enter text.* |
| **A7** | Study nurse | *Click or tap here to enter text.* |
| **A8** | Estimated patient amount at HUS site | *Click or tap here to enter text.* |
| **A9** | Estimated date of SIV | *Click or tap here to enter the date.* |
| **A10** | Estimated ending date of recruitment | *Click or tap here to enter the date.* |
| **Directions to fill out the form:**  **A1** EudraCT number is also acceptable.  **A5** Please specify the HUS hospital or clinic where the study is conducted.  **A6** Names of sub-investigators not relevant.  **A9** HUS Pharmacy requests a separate pharmacy SIV where IMP handling and Pharmacists’ responsibilities are discussed. | | |

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| **B** | | **MEDICINAL PRODUCTS** | | | | |
| Please fill out information for every medicinal product separately. List only products that are **provided or reimbursed by the sponsor**. Please also list products that are not specified as IMP but will be handled or sourced by HUS Pharmacy. Mark these as NON-IMP. In case medicinal product requires special handling (e.g. gmo-products or radiopharmaceuticals), please provide more information in section B5. | | | | | | |
| **B1** Active pharmaceutical ingredient(s)  and strength | | | **B2** Pharmaceutical dosage form and pack size | **B3** Storage  Temperature | **B4** sourcing | |
| Provided by sponsor | Locally sourced |
| *EXAMPLE****:*** *ABC-123 100 mg* | | | *infusion concentrate, 1 vial* | *+2 - +8 °C* |  |  |
| *Click or tap here to enter text.* | | | *Click or tap here to enter text.* | *Temperature* |  |  |
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| **B5** | Additional information | | *Click or tap here to enter text.* | | | |
| **Directions to fill out the form:**  **B4** Details for local sourcing agreed at pharmacy SIV at the latest. | | | | | | |

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| **C** | **HUS PHARMACY SERVICES** | |
| **C1** | Importation of IMP | no  yes |
| **C2** | Storage of IMP at Investigator site | no  yes |
| **C3** | Storage of IMP at HUS Pharmacy | no  yes |
| **C4** | Preparation of patient specific doses | no  yes |
| **C5** | Un-blinded pharmacist duties | no  yes |
| **C6** | Local destruction of IMP at HUS Pharmacy | no  yes |
| **C7** | Other, please specify | *Click or tap here to enter text.* |
| **Directions to fill out the form:**  **C1** Importation of all IMP shipments is a national requirement. HUS Pharmacy is authorized to import IMP from EU/ETA-countries. HUS Pharmacy is authorized to import IMP for use in HUS hospitals. Batch release document for each batch imported is required.  **C2** HUS Pharmacy will receive IMP shipment and forward the IMP shipment to study site shortly after receipt.  **C4** Dose preparation according to HUS Pharmacy practices. HUS Pharmacy instructions, documents and labels are used.  **C5** Un-blinded pharmacist duties and documentation of duties agreed separately at pharmacy initiation visit.  **C6** IMP destruction according to HUS Pharmacy practices. | | |
| **D** | **DOCUMENTATION** | |
| **D1** | Pharmacy manual available | no  yes |
| **D2** | IRT / IxRS is used for study | no  yes, service provider: *Click or tap here to enter text.* |
| **Directions to fill out the form:**  **D1** Please provide Pharmacy manual as an e-mail attachment. You may provide additional documentation that is useful to evaluate the study from the Pharmacy perspective. For academic trials please always provide the study protocol. | | |
| **E** | **ACADEMIC TRIALS** | |
| **E1** | Please describe in English or in Finnish pharmacy services required for the study that are not included in section C. | *Click or tap here to enter text.* |
| **E2** | Study sites | *Click or tap here to enter text.* |
| **Directions to fill out the form:**  **E1** For example labelling, manufacturing or re-packing IMP at HUS Pharmacy.  **E2** Please list all study sites in case you plan for HUS Pharmacy to supply IMP for all Finnish sites. Delivery of IMP to study sites will be planned with the investigator in advance. | | |

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| **Date** | **Summary of changes** |
| 31.10.2022 | Approved for use |
| 18.1.2023 | Amended section D Documentation |

For questions please contact: [HUS-PharmacyClinicalTrials@hus.fi](mailto:HUS-PharmacyClinicalTrials@hus.fi)