This application form has to be submitted together with the initial CTU submission package. For more information please contact Sarah De Sy on +32 89 32 14 23 or An Martens on +32 89 32 14 20 or via clinicaltrials.pharmacy@zol.be.

|  |  |
| --- | --- |
| **Acronym** |       |
| **Study number in ZOL** | Z-       |
| **Principal Investigator in ZOL** |       |

1. **Will the medicine or implant/medical device be administered as part of a medical need program or a compassionate use program?**

[ ]  Yes (go to question 8)

[ ]  No (go to question 2)

1. **Is the investigational product a medicine or an implant/medical device?**

[ ]  Medicine (go to question 3)

[ ]  Implant/medical device (go to question 4)

1. **What are the general characteristics of the medicine?**

|  |  |
| --- | --- |
| **Active ingredient** |       |
| **Dosage** |       |
| **Dosage form** |       |
| **Packaging size** |       |
| **Commercial name** |       |
| **Manufacturer** |       |

* 1. **Who will provide the investigational product?**

[ ]  Pharmacy

[ ]  Sponsor

[ ]  Other:

* 1. **How does the investigational product need to be stored?**

[ ]  At room temperature

[ ]  In the refrigerator (2-8°C)

[ ]  Other:

* 1. **Does the pharmacy need to charge the investigational product?**

[ ]  Yes, to: [ ]  Patient [ ]  RIZIV [ ]  Principal investigator via cost-heading:

[ ]  No

1. **What are the general characteristics of the implant/medical device?**

[ ]  Investigational device (= provided by sponsor free of charge)

[ ]  Control device (= provided by pharmacy from commercial stock OR provided by sponsor free of charge)

[ ]  CE-marked device that is not reimbursed yet (= provided by sponsor free of charge)

[ ]  Co-material (= the device is not being investigated in this clinical trial but it does have to be used in the clinical trial; it is provided by pharmacy from commercial stock or provided by sponsor free of charge)

**COMPANY INFORMATION**

|  |  |  |
| --- | --- | --- |
|  | **Investigational device** | **Control device** |
| **Name** |       |       |
| **Address** |       |       |
| **Contact person** |       |       |
| **Telephone number contact person** |       |       |
| **FAMHP number** |       |       |

**MATERIAL**

|  |  |  |
| --- | --- | --- |
|  | **Investigational device** | **Control device** |
| **Reference number** |       |       |
| **Description** |       |       |
| **Indication** |       |       |
| **Storage conditions** |       |       |
| **Re-sterilizable** | [ ]  Yes, method:      [ ]  No | [ ]  Yes, method:      [ ]  No |
| **Price per unit** |       |       |
| **VAT** |       |       |
| **Packaging unit** |       |       |
| **CE-label number** |       |       |
| **Notification number (only applicable for implants)** |       |       |
| **Contains latex** | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| **NMR-compatible** | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| **Contains DEHP (phthalates)** | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
| **Intended for** | [ ]  Singe use[ ]  Re-use | [ ]  Single use[ ]  Re-use |

|  |  |  |
| --- | --- | --- |
|  | **Investigational device** | **Control device** |
| **Provided by** | [ ]  Pharmacy[ ]  Sponsor[ ]  Other:       | [ ]  Pharmacy[ ]  Sponsor[ ]  Other:       |
| **Reimbursement** | [ ]  Yes Nomenclature number:       Identification code:      [ ]  No  | [ ]  Yes Nomenclature number:       Identification code:      [ ]  No |
| **To be charged by pharmacy** | [ ]  Yes, to: [ ]  Patient [ ]  RIZIV [ ]  Principal investigator, via cost-heading:      [ ]  No | [ ]  Yes, to: [ ]  Patient [ ]  RIZIV [ ]  Principal investigator, via cost-heading:      [ ]  No |

1. **Is co-medication being used?**

[ ]  Yes (go to question 6)

[ ]  No (go to question 7)

1. **What are the general characteristics of the co-medication?**

|  |  |
| --- | --- |
| **Active ingredient** |       |
| **Dosage** |       |
| **Dosage form** |       |
| **Packaging size** |       |
| **Commercial name** |       |
| **Manufacturer** |       |

* 1. **Who will provide the co-medication?**

[ ]  Pharmacy

[ ]  Sponsor

[ ]  Other:

* 1. **How does the co-medication need to be stored?**

[ ]  At room temperature

[ ]  In the refrigerator (2-8°C)

[ ]  Other:

* 1. **Does the pharmacy need to charge the co-medication?**

[ ]  Yes, to: [ ]  Patient [ ]  RIZIV [ ]  Principal investigator via cost-heading:

[ ]  No

1. **What are the expectations from the pharmacy regarding this study?**

[ ]  Transit of the medicine or implant/medical device (= The complete delivery is handed over to the principal investigator. The study team takes care of the correct storage on site and the dispensing to individual patients). After delivery of the medication, the pharmacy needs to contact:

[ ]  Physician, contact information:

[ ]  Secretary, contact information:

[ ]  Nurse, contact information:

[ ]  Other, contact information:

[ ]  Individual delivery of the medicine or implant/medical device (= The complete delivery is being stored in the pharmacy. The pharmacy dispenses individual packages to the patients)

[ ]  Preparation of the medicine\*

* How does the medicine need to be prepared for administration?

* Are specific safety measures necessary during the preparation?

* What is the shelf life of the medicine after preparation for administration?

* Describe the dosage and administration method

*\*For clinical trials, the pharmacy is only allowed to reconstitute medication. The pharmacy does not have a GMP-certificate for the preparation of medicines based on natural resources or other medicines*

[ ]  Monitoring of the storage temperature of the medicine or implant/medical device

[ ]  Via the central system

[ ]  With a study specific temperature logger (provided by the principal investigator or sponsor)

1. **Is the investigational product part of a medical need program (MNP) or part of a compassionate use program (CUP)?**

[ ]  Medical need program (= The medicine is approved by FAMHP, but is being used for another indication in the MNP)

[ ]  Compassionate use program (= The medicine is not approved yet by FAMHP, but is being used to treat seriously ill patients when no other treatments are available)

1. **What are the general characteristics of the medicine that is being used in the MNP or CUP?**

|  |  |
| --- | --- |
| **Active ingredient** |       |
| **Dosage** |       |
| **Dosage form** |       |
| **Packaging size** |       |
| **ATC-code** |       |
| **Commercial name** |       |
| **Manufacturer** |       |

* 1. **How does the medicine need to be stored?**

[ ]  At room temperature

[ ]  In the refrigerator (2-8°C)

[ ]  Other:

* 1. **Is the medicine ready to use?**

[ ]  Yes (go to question 9.3)

[ ]  No (go to question 9.2.1)

* + 1. **How does the medicine need to be prepared for administration?**

* + 1. **Are specific safety measures necessary during the preparation?**

* + 1. **What is the shelf life of the medicine after preparation for administration?**

* 1. **Describe the dosage and administration method**

1. **What are the expectations from the pharmacy regarding this MNP or CUP?**

[ ]  Transit of the medicine. After delivery of the medication, the pharmacy needs to contact:

[ ]  Physician, contact information:

[ ]  Secretary, contact information:

[ ]  Nurse, contact information:

[ ]  Other, contact information:

[ ]  Monitoring of the storage temperature of the medicine or implant/medical device

[ ]  Via the central system

[ ]  With a study specific temperature logger (provided by the principal investigator or sponsor)

|  |
| --- |
| **Additional information for the pharmacy**  |
|        |