|  |
| --- |
| S-number: Click or tap to enter text.Title protocol: Click or tap to enter text..Principal investigator: Click or tap to enter text. |

 Reference date for the date of the annual progress report: **annually after the date of the initial EC/FAMHP approval** (at study level)

Date report: \_\_/\_\_\_/\_\_\_\_

Period of data in report: start date \_\_/\_\_\_/\_\_\_\_ cut-off date\* \_\_/\_\_\_/\_\_\_\_

(\*cut-off date = data in current report were collected until this date)

Data of:

 [ ]  UZ Leuven

 [ ]  Belgian study centers

 [ ]  all participating study centers (in Belgium and abroad if applicable)

1. **Current status:**
* Sign date 1st Informed Consent: \_\_/\_\_\_/\_\_\_\_
* The study has not yet started because of the following reason: Click or tap to enter text.
1. **Evolution of the study since start**

|  |  |  |
| --- | --- | --- |
|  | Number of study participants in UZ Leuven | Number of study participants in all study centers |
| planned |  |  |
| screened (= signed ICF) |  |  |
| included |  |  |
| deceased |  |  |

*Please clarify if there are large differences between the number of planned and included participants:* Click or tap to enter text.

* The study was temporarily interrupted:

[ ]  No

[ ]  Yes, because of:

[ ]  adverse events (specify): Click or tap to enter text.

[ ]  the study design (e.g. phase I/II)

[ ]  other (specify): Click or tap to enter text.

 If study was temporarily interrupted, where:

 [ ]  UZ Leuven

[ ]  Belgian study centers

[ ]  all participating study centers

* The study was terminated early:

[ ]  No

[ ]  Yes\*, because of:

[ ]  adverse events (specify): Click or tap to enter text.

[ ]  insufficient recruitment

[ ]  the study design

[ ]  other (specify): Click or tap to enter text.

*\*If the study is terminated early in all participating centers, the EC should be informed within 15 days.*

* Recruitment has already been terminated:

[ ]  Yes

[ ]  No

* The study has already been terminated as planned:

[ ]  Yes\*

[ ]  No

*\*If the study is terminated as planned in all participating centers, the EC should be informed within 90 days.*

1. **A list of**
* Overview of Serious Adverse Reactions since last report: see appendix 1.
* All amendments and notifications submitted since last report: see appendix 2.
* Protocol deviations: see appendix 3.
1. **Only applicable if the study is not covered by the insurance certificate of UZ Leuven:**

Date of (expected) submission of an update of the insurance certificate indicating the expiry date of this certificate : \_\_/\_\_\_/\_\_\_\_

1. **Conclusion**

- Impact of data in this report on the

\* safety, rights and wellbeing of the participants in the study:
 Click or tap to enter text.

\* integrity and quality of the data:
Click or tap to enter text.

 - Impact of data in this report on the overall benefit-risk ratio of the study:
 Click or tap to enter text.

|  |  |  |
| --- | --- | --- |
| Name principal investigator | Signature | Date |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Appendix 1** – Overview of Serious Adverse Reactions since last progress report

* Study with drug:

 The table view is a suggestion for a schematic overview, adjustments to the layout are possible. The information in the table is the minimum information and can be supplemented with aditional data.

 For multicentric studies in Belgium: please provide a table per site.

 For multinational studies: please provide a table at least per country.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| CountrySite | Case ID / Subject number | SAR description | Start date | Outcome | Reason for seriousness\* | Suspect drug / causality assessment | Daily dose / Route / Formulation | Dates of treatment / treatment duration | Comments |
|  |  |  |  |  |  |  |  |  |  |
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\*: event that results in death, or is life-threatening, or results in persistent or significant disability/incapacity, or requires or prolongs inpatient hospitalization, or is a congenital anomaly or birth defect, or is considered an important medical event

* Study with medical device without CE label or use in study off label:

 Add the European form as annex with all reportable events (these are all serious adverse events related to the medical device and device deficiencies that could possibly have led to a serious adverse event)

* Study without drug or medical device with CE label that is used within the label:

 Overview of all serious adverse events related to the experiment (e.g. related to additional intervention).

**Appendix 2** – Overview of amendments and notifications submitted to the Ethics Committee UZ Leuven

 The table view is a suggestion for a schematic overview, adjustments to the content and layout are possible.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Subject of amendment or notification | Version number and date of protocol and/or ICF (if applicable)  | Date on letter from EC |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| … |  |  |  |

**Appendix 3** – Overview Protocol deviations in UZ Leuven and on trial level (if relevant)

 The table view is a suggestion for a schematic overview, adjustments to the content and layout are possible.

 Attach the action plans.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Site | Subject nr. | Deviation category1 | Deviation title2 | Date deviation occured |
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|  |  |
| --- | --- |
| 1 Deviation categories:A. Safety B. Informed Consent C. EligibilityD. Protocol implementation E. Other, specify  | 2 Deviation title: one line description of deviation (e.g. description of Deviation code on CTC deviation log) |