The due date of the Annual Progress Report (APR) to the Ethics Committee (EC) is based on the date of initial EC approval for study.

|  |
| --- |
| KU/UZ Leuven internal study number (S-nr): Klik of tik om tekst in te voeren.  Protocol title: Klik of tik om tekst in te voeren.  Coordinating/Principal Investigator: Klik of tik om tekst in te voeren.  Report date *(dd/mm/yyyy)*: \_\_/\_\_\_/\_\_\_\_  Reporting period: start date \_\_/\_\_\_/\_\_\_\_ , cut-off date\* \_\_/\_\_\_/\_\_\_\_  *(\*cut-off date = the date up until when data are being reported, this includes the referenced date of data cut-off)*  Reporting data generated by:  KU/UZ Leuven only  All participating Belgian clinical research sites  All participating clinical research sites, Belgian & foreign *(as applicable)* |

1. **Current status**

* Sign date 1st informed consent: - KU/UZ Leuven \_\_/\_\_\_/\_\_\_\_ *(dd/mm/yyyy)*

- Other participating Belgian clinical research site(s): *<Insert research site>* \_\_/\_\_\_/\_\_\_\_ (if applicable, specify for each site)

- International: *<Insert country>* \_\_/\_\_\_/\_\_\_\_ (if applicable, specify for each participating country)

* The study has not started yet due to the following reason(s): *Klik of tik om tekst in te voeren.*
* Subject recruitment is still ongoing:

Yes

No

1. **Progress since study start**

|  |  |  |
| --- | --- | --- |
|  | Number of subjects  in KU/UZ Leuven | Number of subjects overall |
| Planned: |  |  |
| Screened (i.e. consented): |  |  |
| Enrolled: |  |  |
| Deceased (since the previous APR)\* |  |  |

\* Only deaths of participants who were participating in the study at that time of their death should be listed and reported in this APR.

Please tick this box if the protocol of the study states that deaths do not require immediate reporting

Please explain any major discrepancies between the number of planned & enrolled subjects: *Klik of tik om tekst in te voeren.*

* The study was temporarily halted:

No

Yes, due to:

Adverse events (please specify): *Klik of tik om tekst in te voeren.*

Study design (e.g. phase I/II)

Other (please specify): *Klik of tik om tekst in te voeren.*

The study was temporarily halted at the following participating research sites:

KU/UZ Leuven only

All participating Belgian clinical research sites

All participating clinical research sites, Belgian & foreign (as applicable)

* The study was terminated prematurely:

No

Yes\*, due to:

Adverse events (please specify): *Klik of tik om tekst in te voeren.*

Poor recruitment

Study design

Other (please specify): *Klik of tik om tekst in te voeren.*

*\*Central/local Ethics Committee(s) must be informed within 15 calendar days in case of early termination of the study in all participating research sites.*

* The study was completed as planned per protocol:

Yes\*

No

*\*Central/local Ethics Committee(s) must be informed within 90 calendar days upon completion of the study in all participating research sites.*

1. **Overviews**

* Appendix 1: Overview of reportable safety events since previous APR
* Appendix 2: Overview of all amended/revised study documents and notifications submitted to the Ethics Committee since previous APR: please refer to appendix 2
* Appendix 3: Overview of protocol deviations/violations

1. **Insurance\***

*\*This section only applies to studies that are not covered by UZ Leuven’s clinical research insurance policy. Delete section if not relevant.*

* Current evidence of clinical research insurance expires on (specify date): \_\_/\_\_\_/\_\_\_\_
* Expected submission date for documentation evidencing continuous and adequate insurance for the clinical: \_\_/\_\_\_/\_\_\_\_

1. **Conclusion**

Impact of the reported data on:

* Safety, rights and wellbeing of study participants:

*Klik of tik om tekst in te voeren.*

* Integrity and quality of study data:

*Klik of tik om tekst in te voeren.*

* Overall risk-benefit ratio of the study:

*Klik of tik om tekst in te voeren.*

|  |  |  |
| --- | --- | --- |
| …………………………. | …………………………. | …………………………. |
| Name of Coordinating/Principal Investigator | Signature | Date *(dd/mm/yyyy)* |

**Appendix 1 – Overview of reportable safety events since previous APR**

* Overview of serious undesirable events related to the clinical research experiment (e.g. related to an additional intervention)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Country**  **Site** | **Case ID / Subject number** | **SAE description** | **Start date** | **Outcome** | **Reason for seriousness\*** | **Causality assessment** | **Comments** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

* For PMCF studies with no burdensome and/or invasive procedures: Overview of Serious Adverse Device Effects (SADEs) and any Device Deficiencies (DDs) that could possibly have led to an SADE if:
* i. no action had been taken, or
* ii. no intervention had occurred, or
* iii. circumstances would have been less fortunate

**Appendix 2** – **Overview of all amended/revised study documents and notifications submitted to the Ethics Committee since previous APR**

The below template table may be customized to fit study-specific needs.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Revised/amended document | Version number & date | Date notified to EC *(dd/mm/yyyy)* |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| … |  |  |  |

**Appendix 3 – Overview of protocol deviations/violations**

The below template table may be customized to fit study-specific needs. For protocol violations, please also attach Corrective Actions & Preventive Actions (CAPAs).  
.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Site** | **Subject nbr.** | **Deviation/ violation category\*** *(A, B, C, D or E)* | **Description of non-compliance** *(summarize non-compliance a single sentence)* | **Date non-compliance occurred** *(dd/mm/yyyy)* |
|  |  |  |  |  |
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*\*Deviation categories: A. Safety, B. Informed consent, C. Eligibility, D. Protocol implementation, E. Other*