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*