**Annual progress report - Template**

* This document has to be completed by the principal investigator or the sponsor of the study.
* This document must be submitted to the Ethics Committee on the anniversary date of the final ethics approval every year for the duration of the study.
* Each section must be completed. If a question does not apply to your study, enter “NA” in the box next to the question.

# General information of the study

|  |  |
| --- | --- |
| Reference number of the Ethics Committee: | 20xx/xxx |
| Full title of the study: |  |
| EU CT number/BUN[[1]](#footnote-1), if applicable: |  |
| Study code: |  |
| Date of the final approval: |  |

# Details of the person who completed this report

|  |  |
| --- | --- |
| Name: |  |
| Institution: |  |
| E-mail: |  |
| Phone number: |  |

# Start and end dates

|  |  |
| --- | --- |
| Has the study started in Belgium? | [ ]  Yes [ ]  No |
| If yes, when did the study start in Belgium?  |  |
| If not, what are the reasons for this? |  |
| What is the expected start date? |  |
| Has the study ended in Belgium? | [ ]  Yes [ ]  No |
| If yes and applicable, has a “Declaration of end of study” been submitted ? |  |
| If not, what is the expected completion date? |  |
| If you expect the study to last beyond the planned completion date, what is(are) the reason(s)? *Please note: this should be submitted to the EC* |  |
| If you do not expect the study to be completed, please provide an explanation |  |

# Registration on a public database

|  |  |
| --- | --- |
| Is your study registered on a public database platform? (e.g.: Clinicaltrials.gov or clinicaltrialsregister.eu) | [ ]  Yes [ ]  No |
| If yes, please provide the name of the public database and the registration number |  |
| If not, what is(are) the reason(s) for not registering your study? |  |

# Recruitment of participants

|  |  |
| --- | --- |
| Number of participants **expected:** |  |
| Number of participants **screened:** |  |
| Number of participants **enrolled:** |  |
| Number of participants **in follow-up:** |  |
| Number of participants **completed:** |  |
| Number of withdrawals[[2]](#footnote-2) from study due to |  |
| Withdrawal of consent: |  |
| Loss of follow-up: |  |
| Death (where not the primary outcome): |  |
| Other causes: |  |
| Total number of withdrawals: |  |
| Number of treatment failures[[3]](#footnote-3) (prior to reaching primary outcome) due to |  |
| Adverse events: |  |
| Lack of efficacy: |  |
| Total number of treatment failures: |  |

|  |  |
| --- | --- |
| Have there been any serious difficulties recruiting participants or accessing samples ? | [ ]  Yes [ ]  No |
| If yes, please provide some details: |  |

|  |  |
| --- | --- |
| Do you plan to increase the planned recruitment of participants into the study? | [ ]  Yes [ ]  No |
| *Please note, any changes to the recruitment methodology has to be notified to the EC as a substantial modification*  |  |

# Substantial modification

|  |  |
| --- | --- |
| Have any substantial modifications been made during the last 12 months? | [ ]  Yes [ ]  No |
| If yes, please give the date and amendment number or description for each substantial modification made: |  |
| Have any non-substantial modifications (ethical approval not required) been made during the last 12 months? | [ ]  Yes [ ]  No |
| If yes, please provide details: |  |

# Safety of the participants

|  |  |
| --- | --- |
| Have there been any serious adverse events (SAEs) in this study? | [ ]  Yes [ ]  No |
| If yes, have these SAEs been notified to the EC? |  |
| If not, please submit details with this report and give reasons for this late notification. |  |

|  |  |
| --- | --- |
| Have any additional concerns arisen about the safety of participants in this study? | [ ]  Yes [ ]  No |
| If yes, please provide details and say how the concerns have been addressed. |  |

**If this study is not related to an IMP[[4]](#footnote-4), please go to section 8**

|  |  |
| --- | --- |
| Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial in Belgium? | [ ]  Yes [ ]  No |
| If yes, have they been notified to the EC? | [ ]  Yes [ ]  No |
| If the EC has not been notified, please submit a detailed report and give reasons for this late notification. |  |
| Has the Development Safety Update Report (DSUR) been submitted?*Sponsors are required to submit a DSUR within one year of the Development International Birth Date (DIBD – the date of first authorisation of a clinical trial in any country worldwide) and provide annual DSUR submissions until all open clinical studies have ended (the final clinical study is completed and its study report has been submitted).* | [ ]  Yes [ ]  No |

|  |  |
| --- | --- |
| Does the study have a data safety monitoring board? | [ ]  Yes [ ]  No |
| If yes, has this board given an opinion?  | [ ]  Yes [ ]  No |
| If this board has not yet given an opinion, please indicate when an opinion will be given. |  |

# Serious breaches[[5]](#footnote-5) of the protocol

|  |  |
| --- | --- |
| Have there been any serious breaches that the EC has not been informed of?  | [ ]  Yes [ ]  No |
| If yes, please provide the related report(s) and give reasons for this late notification. |  |

# Insurance

|  |  |
| --- | --- |
| Is the insurance of the study still valid? | Valid from to  |

# Risk/benefit

|  |  |
| --- | --- |
| Is the risk/benefit balance still positive?  | [ ]  Yes [ ]  No |

# Other issues

|  |  |
| --- | --- |
| Are there any other issues in the study that you wish to report to the EC? | [ ]  Yes [ ]  No |
| If yes, please provide details: |  |

# Declaration

|  |  |
| --- | --- |
| Signature:[ ]  Principal investigator [ ]  Sponsor |  |
| Name: |  |
| Date: |  |

1. BUN: Belgian unique number, e.g. B707\*\*\*\*\*\*\*\*\*\* [↑](#footnote-ref-1)
2. Withdrawal: The participant abandoned the study [↑](#footnote-ref-2)
3. Treatment failure: As defined in the protocol [↑](#footnote-ref-3)
4. Investigational medical product [↑](#footnote-ref-4)
5. Serious breaches: Any deviation from the approved protocol version or the clinical trial regulation that is likely to affect the safety, rights of trial participants and/or data reliability and robustness to a significant degree in a clinical trial [↑](#footnote-ref-5)