|  |  |  |
| --- | --- | --- |
| Protocol number: protocolnummer  ALIAS: ALIAS  Eudract Number: Eudract nummer  PI: PI |  |  |

**STUDY PROGRESS REPORT**

**1. Details of Primary Investigator**

|  |  |
| --- | --- |
| Name: |  |
| **Address:** |  |
| **Telephone:** |  |
| **Fax:** |  |
| **E-mail:** |  |

**2. Details of study**

|  |  |
| --- | --- |
| **Full title of study:** |  |
| **Protocol number:** |  |
| **EudraCT Number:** |  |
| **EC reference number:** |  |

**Date of report:**

**Period of data collection in report:** start date: cut-off date:

*(cut-off date: gegevens in huidig rapport werden verzameld tot deze datum)*

#### 3. Commencement and termination dates

|  |  |
| --- | --- |
| **Has the study started ?** | Yes / No |
| **If yes, what was the actual start date?** |  |
| **If no, what are the reasons for the study not commencing?**  **What is the expected start date?** |  |

|  |  |
| --- | --- |
| **Has the study finished?** | Yes / No |
| **If no, what is the expected completion date?** |  |
| If you do not expect the study to be completed, give reason(s) |  |

**4. Site information**

|  |  |  |
| --- | --- | --- |
| **Number of research sites proposed in original application:** | |  |
| **Number of research sites recruited to date:** | |  |
| **Do you plan to increase the total number of sites proposed for the study?** | Yes / No | |

**5. Recruitment of participants**

|  |  |
| --- | --- |
| \* Number of participants recruited: | *Proposed in original application:*  *Actual number recruited to date:* |
| \* Number of participants completing trial: | *Actual number completed to date:* |
| \* Number of withdrawals from trial to date due to: | |
| (a) withdrawal of consent: |  |
| (b) loss to follow-up: |  |
| (c) death (where not the primary outcome): |  |
| Total study withdrawals: |  |
|  |  |
| \*Number of treatment failures to date (prior to reaching primary outcome) due to: |  |
| (a) adverse events: |  |
| (b) lack of efficacy: |  |
| Total treatment failures: |  |

|  |  |  |
| --- | --- | --- |
| **Have there been any serious difficulties in recruiting participants?** | | Yes / No |
| **If yes, give details:** |  | |
| **Do you plan to increase the planned recruitment of participants into the study?** | | Yes / No |

6. Safety reports

|  |  |
| --- | --- |
| Have there been any Suspected Unexpected Serious Adverse Reactions (SUSARs) in this trial ? | *Yes / No* |
| **Have these SUSARs been notified to the Ethics Committee within 7/15 days under Article 17 of EU Directive?** | Yes / No |
| **What is the reporting date for periodic safety reports to the main Ethics COmmittee during this trial?** |  |
| **Has the Annual Safety Report been submitted?** | Yes / No / Not yet due |
| **When is the next ASR due?** |  |

**7. Amendments**

|  |  |
| --- | --- |
| **Have any substantial amendments been made to the trial during the year?** | Yes / No |
| **If yes, please give the date and amendment number for each substantial amendment made.** | *Geef hier een overzicht van alle ingediende amendementen en notificaties sinds laatste rapport (met vermelding van versienummer en datum van protocol en/of ICF).* |

**8. Serious breaches of the protocol or Good Clinical Practice**

|  |  |
| --- | --- |
| **Have any serious breaches of the protocol or GCP occurred in relation to this trial during the year?** | Yes / No |
| **If yes, please give the date of each notification to Ethics Committee.** |  |

**9. Conclusion**

|  |  |
| --- | --- |
| **Do reported data have an impact on the safety, the rights and the well-being of the trial subjects?** | Yes / No |
| **Do reported data have an impact on the integrity and/or quality of trial related data?** | Yes / No |
| **Do reported data have an impact on the overall benefit-risk ratio of the study?** | Yes / No |

|  |  |
| --- | --- |
| **Signature of Primary Investigator:** |  |
| **Print name:** |  |
| **Date of submission:** |  |

**Appendix I: Overview of all SAE’s since last study progress report**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Site** | **Subject no.** | **SAE** | **SAE seriousness category** | **Start date** | **Outcome** | **Suspect drug/causality assessment** |
|  |  |  |  |  |  |  |

**Appendix II: Overview of all protocol devations since last study progress report**

Deviation category:

A: consent procedures

B: inclusion/exclusion criteria

C: concomitant medication/therapy

D: laboratory assessments/procedures

E: study procedures/evaluations

F: serious adverse event reporting

G: randomization procedures

H: visit schedule/interval

I: study drug dosing

J: other

| **Site** | **Ref no.** | **Subject no.** | **Date deviation occured** | **Deviation description** | **Deviation category** | **Class** | **Corrective/ Preventive action** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |