**Annex XI**

**Annual follow-up report of the clinical trial**

Version 10th December 2019;

Previous versions: 18th April 2017; 23rd June 2017

|  |  |
| --- | --- |
| REPORT DATE |  |
| REPORT PERIOD 1 |  |

|  |  |
| --- | --- |
| **General clinical trial details** | |
| TITLE |  |
| EudraCT No. |  |
| *Sponsor protocol code* |  |
| Sponsor |  |
| Phase | Select an option. |

|  |  |
| --- | --- |
| **Current status of clinical trial globally** | |
| Planned Number of Subjects |  |
| Number of Subjects Included |  |
| Number of Subjects Ended |  |

|  |  |
| --- | --- |
| **Current status of clinical trial in Spain** | |
| Date of Authorization | Click here to write a date |
| Current Status | Select an option. |
| Early Termination | Select an option. |
| Date | Click here to write a date |
| Cause |  |

**The insurance premium of the Insurance Policy covering this clinical trial is paid until (indicate the date)** (in case of a low intervention clinical trial this sentence is not necessary)

|  |
| --- |
| **Information on recruitment in Spain (Cumulative data should be included. It is optional to add between parentheses last year data)**  (copy and paste the site row as many times as the number of participating sites. Please, keep the format of the original table) |

| Site name | Site status | Reason2 | Nº of subjects screened | Screening failures | Nº of subjects included | Nº of Subjects Completed | Nº of withdrawn and discontinued | Reasons for withdrawals and discontinuations3 | Nº of Serious breaches |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Elija un elemento. |  |  |  |  |  |  | ☐ Low Efficacy  ☐ Serious Adverse Event  ☐ Protocol Violation  ☐ Unknown  ☐ Other Causes |  |
| TOTAL FROM ALL SITES | | |  |  |  |  |  | ☐Low Efficacy  ☐ Serious Adverse Event  ☐ Protocol Violation  ☐ Unknown  ☐ Other Causes |  |

Check “Glossary” section in order to fill in properly all fields

**GLOSSARY**

*Planned Number of Subjects*: sample size defined in the protocol.

*Number of Subjects Included* (*entered*) = number of recruited subjects – number of screen failures.

*Number of Subjects Ended* = number of completed subjects + number of withdrawals and discontinuations.

*Number of Subjects recruited* (*screened*): number of subjects who have signed the informed consent.

S*creening failures*: number of subjects who having signed the informed consent, finally do not meet the selection criteria to be included in the clinical trial. Number of subjects who decide to withdraw informed consent before their inclusion.

Number of Subjects *completed*: number of subjects who have ended all defined follow-up procedures for the clinical trial.

Number of *withdrawal* and discontinuations (*dropout*): It includes the number of patients withdrawn by the investigator and the number of patients that have discontinued the clinical trial on his own decision, without being subject to any additional clinical trial follow-up procedure from the date of discontinuation. Note: if a patient stops the treatment but continues the follow up according to the clinical trial procedures, he/she should not be a withdrawal nor a discontinuation.