**Annex XII**

Version 29 June 2020

|  |
| --- |
| **Report on exceptional measures adopted to manage the problems derived from the COVID-19 emergency** |

|  |  |
| --- | --- |
| REPORT DATE |  |

|  |  |
| --- | --- |
| **General clinical trial data** | |
| Title |  |
| EudraCT Number |  |
| Protocol code (sponsor) |  |
| Sponsor |  |
| Phase | Choose an element |

|  |
| --- |
| **Exceptional measures adopted for the study (include all measures adopted although they had been previously notified to AEMPS or to CEIm)**  **Provide the details on the adopted measures in each section**   * Effective date * End of measure date * Risk analysis and justification of each group of measures |
| Select one of the following options:  Attach sponsor/CRO communication to the affected sites  In case of a general communication to all participant sites, include the communication(s) and include an introduction, e.g:  *On dd-mm-yyyy the communication included in Annex I was sent to all particpant sites. This Annex includes the justification and risk assessment. The effective date of these measures was dd-mm-yyyy.*  In cases where there is no global communication sent to the investigators of the participant sites, please list each measure indicating: effective date, risk analysis and justification, and end of measure date. |
|  |
|  |

Below, detail the impact of these measures in the study in Spain:

|  |  |
| --- | --- |
| **1. Adopted exceptional measures related to onsite visits programmed for the patients** | |
| Sites with visits of the subjects postponed(out of the window allowed in the protocol) | 1. *X of Y* 2. *(Y: total number of active sites in the study)* |
| Sites with visits of the subjects cancelled (not carried out) | *X of Y* |
| Sites with onsite visits transformed in remote visits | 1. *X of Y* |
| Sites where tests of the study (e.g. labs, etc) have been carried out in different sites to the study site (e.g. primary care physician) or to those established in protocol/ manuals | *X of Y*  *(specify the tests of the study impacted)* |
| Sites where personnel of the study site (investigator, nurse, etc) have gone to patient home | 1. *X of Y* |
| Sites having used clinical assistance/home nursing vendors | 1. *X of Y*   *Specify names of the vendor companies* |
| Sites which have carried out patient visits but not having followed all the study procedures programmed for the visit | *X of Y* |
|  |  |
| **2. Adopted exceptional measures related to recruitment of new patients** | |
| Indicate if the sponsor has halted recruitment | *Yes/No*  *If applicable:*  *Date of halt of recruitment:*  *Date of re-start of recruitment:* |
| Other measures related to patient recruitment |  |
|  |  |
| **3. Adopted exceptional measures related to access to clinical trial treatment** | |
| The trial has been halted because of lack of supply of any medicinal product | *Yes/No*  *If yes, indicate the date when it was notified to AEMPS and CEIm* |
| The treatment has been interrrupted in some patients:   1. Temporary 2. Permanently | 1. *Yes/No* 2. *Yes/No*   *If yes, indicate the reason (when different to supply issues)* |
| Sites where study treatment has been shipped to patient home using a shipment vendor provided by the sponsor | *X of Y (Y: total of active sites in the study)*  *Specify name of the vendor* |
| Sites where study treatment has been shipped to patient home using a shipment vendor provided by the site | *X of Y (Y: total of active sites in the study)*  *Specify name of the vendor* |
| Other measures related to access to clin. trial treatment |  |
|  |  |
| **4. Adopted exceptional measures related to Informed Consent** | |
| Re-consent of the study: In studies already started, in order to continue with the study, informed consent has been got remotely (e.g. by phone, or video-conference, etc.) | *Yes/No/Not applicable*  *X of Y (Y Y: total of active sites in the study)*  *If re-consent during Covid-19 emergency has been needed, specify instructions.* |
| Other measures related to the informed consent of the clinical trial |  |
| **5. Adopted exceptional measures related to Monitoring Visits** | |
| The Monitoring Plan of the study has been updated during this period to allow remote monitoring visits, centralized monitoring, or other measures | *Yes/No (if applicable, include summary of changes)* |
| Other types of visits replaced by remote visits (e.g. site initiation, closures, selection, etc.) | *Yes/No (if applicable, include summary of changes)* |
| Other measures related to access to monitoring visits of the study. if remote monitoring with source data verification has been carried out, specify involved sites, effective period and method used (eg. remote access to electronic clinical history through video-conference, scan of source documentation and shipment to monitor, phone call or other type) |  |
|  |  |
| **6. Adopted exceptional measures related to transference of patients from one site to another** | |
| Transference of patients from one site to another site of the trial or to a different site. Specify | *Yes/No (if applicable, specify detail of the cases)* |
| Other measures related to transference of patients from some sites to others (eg. opening new sites of the clinical trial) |  |
|  |  |
| **7. Other exceptional measures adopted to manage Covid-19 crisis** | |
| <Include adopted measure> |  |
| <Include adopted measure> |  |