

Declaration of the End of a Clinical Trial on a Medicinal Product for Human Use to the Research Ethics Committee.

**This form should be completed by the Sponsor.
It should be submitted to the recognised REC, which gave the favorable opinion within 90-days of the conclusion (last person - last visit) of the trial.**

A.1 TRIAL IDENTIFICATION

| | |
|--|--|
| EudraCT no.: | |
| Title of clinical trial: | |
| REC reference no.: | |
| Name of REC to which report is being submitted | |
| Submission date: | |

A.2 TRIAL DURATION

| | | | |
|------------|-----------------------------------|-------|------------|
| Start date | <i>(first person first visit)</i> | | dd/mm/yyyy |
| End date | <i>(last person last visit)</i> | | dd/mm/yyyy |
| Duration | <i>(years / months)</i> | Years | Months |

B. APPLICANT IDENTIFICATION

| | |
|--------------------|--|
| B.1 Sponsor | |
| Name: | |
| Address: | |
| Tel: | |
| Fax: | |
| E-mail: | |

C. CIRCUMSTANCES OF ENDING OF CLINICAL TRIAL

| | |
|--|--|
| C.1 Has this clinical trial ended prematurely? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If Yes, please specify the reasons for ending the trial prematurely. | |
| | |

| | |
|--|--|
| C.2 Is this a temporary halt to the trial? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If Yes, please specify the reasons for temporarily halting the clinical trial and, if possible, identify when you expect the clinical trial to re-start. | |
| | |

| | |
|--|--|
| C.3 Are there any potential implications for research participants as a result of terminating/halting the clinical trial prematurely? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If Yes, please describe the steps taken to address them. | |
| | |

D. FINAL REPORT ON THE RESEARCH

D.1 Is a summary of the final report on the research enclosed with this form?

Yes **No**

If No, please submit a copy to the REC within twelve months of the end of the clinical trial.

DECLARATION

I confirm that the information contained in this form is accurate to the best of my knowledge and I take full responsibility for it.

Signature: _____

Print Name: _____

Date: _____ (dd/mm/yyyy)