**Declaration of the end of a clinical trial**

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| *For official use:* | |
| **Date of receipt** |  |
| **Competent authority, Ethics Committee registration number** |  |

|  |  |
| --- | --- |
| *To be filled in by the applicant:* | |
| **Member State in which the declaration is being made** |  |
| **EudraCT number** |  |
| **Sponsor’s protocol code number** |  |
| **Full title of the trial** |  |

**Applicant identification (please tick the appropriate box)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **DECLARATION FOR THE COMPETANT AUTHORITY**  Sponsor: ………..  Legal representative of the sponsor  Person or organization authorized by the sponsor to make the application. In that case, complete below | | |  | **DECLARATION FOR THE ETHICS COMMITTEE**  Sponsor: ………..  Legal representative of the sponsor  Person or organization authorized by the sponsor to make the application. In that case, complete below | | |
|  | |  |  |  | |  |
|  | |  |  | **In case of investigator in charge of the application, complete the next page** | | |
|  | |  |  |  | |  |
| **Organization** |  | |  | **Organization** |  | |
| **Name of the**  **person to contact** |  | |  | **Name of the**  **person to contact** |  | |
| **Street Address** |  | |  | **Street Address** |  | |
| **Town/City** |  | |  | **Town/City** |  | |
| **Post Code** |  | |  | **Post Code** |  | |
| **Telephone**  **Number** |  | |  | **Telephone**  **Number** |  | |
| **Fax** |  | |  | **Fax** |  | |
| **E-mail** |  | |  | **E-mail** |  | |
|  | |  |  |  | |  |

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|  |  |  | **DECLARATION FOR THE ETHICS COMMITTEE**  **Investigator in charge of the application:**  Coordinating investigator (for multicenter trial):  🡪  Principal investigator (for multicenter trial):  🡪  Person or organization authorized by the sponsor to make the application. In that case, complete below | |
|  |  |  |  |  |
|  |  |  | **Name** |  |
|  |  |  | **Street Address** |  |
|  |  |  | **Town/City** |  |
|  |  |  | **Post Code** |  |
|  |  |  | **Telephone**  **Number** |  |
|  |  |  | **Fax** |  |
|  |  |  | **E-mail** |  |

**End of trial**

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | **Date of the end  of the trial (dd/mm/yyyy)** |
| Is the end of the trial in the Member state? | yes | no |  |
| Is the end of the complete trial in all countries concerned by the trial? | yes  yes | no  no |  |
| Is it a premature ending of the trial?  Is it a temporary halt of the trial? | yes | no |  |
| If yes, complete the following boxes:   * What is (are) the reason(s) for the halt or premature ending? * Safety * Lack of efficacy * The trial has not commenced * Other | yes  yes  yes  yes | no  no  no  no |  |
| If yes, specify | | | |
| Number of patients still receiving treatment at time of halting or premature termination on the MS concerned by the declaration: | | |  |

And briefly describe in an annex (free text):

* The justification for a halt or premature ending of the trial
* The proposed management of patients receiving treatment at time of the halt or of study termination
* The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product

I hereby confirm that/confirm \* on behalf of the sponsor\* that (delete which is not applicable)

* The above information given on this declaration is correct
* That a summary of the clinical trial report will be submitted to the competent authority and ethics committee concerned as soon as available and within a 1 year deadline after the end of the trial in all countries.

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| **APPLICANT (as stated on first page):**  Date:  Signature:  Print name: | **APPLICANT (as stated on first page):**  Date:  Signature:  Print name: |