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| **ΦΑΡΜΑΚΕΥΤΙΚΕΣ ΥΠΗΡΕΣΙΕΣ** |
| **ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ** |
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| **ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ** |  | **PHARMACEUTICAL SERVICES** |
| **REPUBLIC OF CYPRUS** |  | **MINISTRY OF HEALTH** |

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| **DECLARATION OF THE END OF A CLINICAL TRIAL** |

*The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law*

*The Medicinal Products for Human Use (Good Clinical Practice) Regulations*

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| **ΔΗΛΩΣΗ ΠΕΡΑΤΩΣΗΣ ΚΛΙΝΙΚΗΣ ΔΟΚΙΜΗΣ** |

*Ο περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμος*

*Οι περί Φαρμάκων Ανθρώπινης Χρήσης (Ορθή Κλινική Πρακτική) Κανονισμοί*

*This declaration is addressed to (tick the appropriate box):*

|  |  |
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| **Registrar of the Drugs Council**  **Pharmaceutical Services**  **Ministry of Health**  **Lefkosia 1475, CYPRUS**  **Tel.: +357 22 608 635**  **+357 22 608 603**  **Fax: +357 22 608 649** |  |

*For official use*

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| Date of receipt : |

# Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial[[1]](#footnote-1)*)

***To be filled in by the applicant***

1. **MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE :**

**REPUBLIC OF CYPRUS**

1. **TRIAL IDENTIFICATION**

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| * 1. **EudraCT number : (..)**   2. **Sponsor’s protocol code number: (..)**   3. **Full title of the trial :** |

1. **APPLICANT IDENTIFICATION** (please tick the appropriate box)

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| * 1. **DECLARATION FOR THE COMPETENT AUTHORITY** |
| * + 1. Sponsor     2. Legal representative of the sponsor     3. Person or organisation authorised by the sponsor to make the application.     4. **Complete below**:        1. Organisation :        2. Name of person to contact :        3. Address :        4. Telephone number :        5. Fax number :        6. E-mail |

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| * 1. **DECLARATION FOR THE ETHICS COMMITTEE** |
| * + 1. Sponsor     2. Legal representative of the sponsor     3. Person or organisation authorised by the sponsor to make the application.     4. Investigator in charge of the application if applicable[[2]](#footnote-2): * Co-ordinating investigator (for multicentre trial): * Principal investigator (for single centre trial):   + 1. **Complete below** :        1. Organisation:        2. Name :        3. Address :        4. Telephone number :        5. Fax number :        6. E-mail : |

1. **END OF TRIAL**

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| * 1. **Date of the end of the complete trial in all countries concerned by the trial**? |
| * + 1. (YYYY/MM/DD): |

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| * 1. **Is it an early termination?[[3]](#footnote-3)** yes no |
| * + 1. If yes, give date (YYYY/MM/DD):     2. Briefly describe in an annex (free text):        1. The justification for early termination of the trial;        2. Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;        3. The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product. |

1. **SIGNATURE OF THE APPLICANT IN THE MEMBER STATE**

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| * 1. 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; and * That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[[4]](#footnote-4) |

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| * 1. **APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1) |
| * + 1. Date :     2. Signature :     3. Print name: |

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| * 1. **APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:** |
| * + 1. Date :     2. Signature :     3. Print name: |

1. OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'. [↑](#footnote-ref-1)
2. According to national legislation. [↑](#footnote-ref-2)
3. Cf. Section 4.2. of the detailed guidance CT-1. [↑](#footnote-ref-3)
4. Section 4.3. of the detailed guidance CT-1. [↑](#footnote-ref-4)