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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)