REQUEST FOR AUTHORISATION OF A CLINICAL TRIAL ON A MEDICINAL PRODUCT FOR HUMAN USE TO THE COMPETENT AUTHORITIES AND FOR OPINION OF THE ETHICS COMMITTEES IN THE COMMUNITY

For official use:

Date of receiving the request : Date of request for information to make it valid :	Date of request for additional information :	Grounds for non acceptance/ negative opinion : yes ☐ no ☐ If yes, date :
Date of valid application : Date of start of procedure :	Date of receipt of additional / amended information :	Authorisation/ positive opinion : yes ☐ no ☐ If yes, date:
Competent authority, Ethics Committee registration number :		

To be filled in by the applicant:
This form is common for request for authorisation from the Competent Authority and for the opinion from an Ethics Committee. Please indicate the relevant purpose in a box below.

REQUEST FOR AUTHORISATION TO THE COMPETENT AUTHORITIES: ✓

A. TRIAL IDENTIFICATION

Member State in which the submission is being made : SWEDEN

EudraCT number[1]: **2006-002553-80**

Full title of the trial:
ADHD hos intagna inom Kriminalvården – förekomst/diagnos/behandling/uppföljning

Sponsor's protocol code number[2]: **ADHD Norrtälje 2006**

Sponsor's protocol version[2]: **1.0**

Sponsor's protocol date[2]: **2006-05-11**

Name or abbreviated title of the trial where available:

ISRCTN number[3], if available :

[1] Append the EudraCT number confirmation receipt

[2] Any translation of the protocol should be assigned the same date and version as those in the original document.

[3] International Standard Randomised Controlled Trial Number

B. IDENTIFICATION OF THE SPONSOR RESPONSIBLE FOR THE REQUEST

B1. Sponsor	
Name of organisation :	Karolinska Universitetssjukhuset
Name of the person to contact:	Nils Lindefors
Address :	Psykiatri Karolinska, Hus R5 Stockholm 171 76 SWEDEN
Telephone number :	08-517 750 13
Fax number :	08-517 717 17
e-mail:	nils.lindefors@sll.se
Status of the sponsor :	commercial[5] ☐ non commercial ✓

B2. Legal representative[4] of the sponsor in the Community for the purpose of this trial (if different from the sponsor)
Name of organisation :
Name of the person to contact:
Address :
Telephone number :
Fax number :
e-mail:

[4] : In accordance with article 19 of Directive 2001/20/EC

[5] : A commercial sponsor is a person or organisation that takes responsibility for a trial which at the time of the application is part of the development programme for a marketing authorisation of a medicinal product.

G. GENERAL INFORMATION ON THE TRIAL

Medical condition or disease under investigation
Specify the medical condition (free text) : Attention Deficit Hyperactivity Disorder (ADHD)   ICD classification code[12] : MedDRA classification code-Version [13] : MedDRA classification code-Level [13] : MedDRA classification code-Classification [13] : Is it a rare disease[14] ? yes ☐ no ✓

Objective of the trial
Main objective : Syftet är att utvärdera effekten av metylfenidat (Concerta) kombinerat med sedvanlig psykosocial behandling på ADHD-symtom hos en grupp vuxna män med ADHD, intagna inom Kriminalvården. De aktuella personerna är samtliga intagna på Norrtäljeanstalten.   Secondary objectives : Utvärdera effekten av metylfenidat (Concerta) kombinerat med sedvanlig psykosocial behandling på global funktionsnivå, neuropsykologiska funktionsmått, egenskattade ADHD-symtom och livskvalitet hos en grupp vuxna män med ADHD, intagna på Norrtäljeanstalten. Vi kommer även att undersöka i vilken utsträckning personerna får fortsatt läkemedelsbehandling efter studiens slut.

[12] Source : World Health Organization

[13] The information on the ICD and MedDRA classification is optional. When both classifications are available only one should be provided; in this case applicants are encouraged to provide the MedDRA classification.

Design of the trial

Randomised :	yes ☐ no ✓		
Controlled :	yes ☐ no ✓		
• If yes, specifiy :			
Open :	yes ☐ no ☐		
Single blind :	yes ☐ no ☐	Double blind :	yes ☐ no ☐
Parallel group :	yes ☐ no ☐	Cross over :	yes ☐ no ☐
Other :	yes ☐ no ☐		
If yes, specify :			

• Specify the comparator :	
- (an) other medicinal product(s)	yes ☐ no ☐
- placebo	yes ☐ no ☐
- other	yes ☐ no ☐
If yes, specify :	

Single site (see also section I) :	yes ✓ no ☐
Multiple site (see also section I) :	yes ☐ no ✓
Multiple Member States :	yes ☐ no ✓
Does this trial involve third countries ?	yes ☐ no ✓

[15] according to page 5 of Community guideline CPMP/ICH/291/95