EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

European network of paediatric research (EnprEMA)

Recognition criteria for self assessment

The European Medicines Agency is tasked with developing a European paediatric network of existing national and European networks, investigators and centers with specific expertise in the performance of studies in the paediatric population.

Following a test pilot phase, public consultation and the outcome of the second workshop with participants of 28 networks and/or clinical trial centres in March 2010, recognition criteria have been finalised which will have to be fulfilled by existing networks to become a member of the European paediatric network. All networks wishing to become a member of EnprEMA are invited to perform self-assessment and to send the filled-in document to the European Medicines Agency.

The document should be sent to Merja.Heikkurinen@ema.europa.eu

END OF SELF-ASSESSMENT PERIOD	31 July 2010

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An agency of the European Union

EnprEMA

European network of paediatric research at the European Medicines Agency

Recognition criteria for self-assessment

The European Paediatric Regulation (EC) No 1901/2006, as amended, calls for the fostering of high-quality ethical research on medicinal products for use in children. This should be achieved through efficient inter-network and stakeholder collaboration. To meet this objective, a European paediatric research network is to be formed of national and European networks, investigators and centres with specific expertise in performing drug trials in the paediatric population. General information can be found at:

http://www.emea.europa.eu/htms/human/paediatrics/network.htm

Minimum criteria that have to be fulfilled to be recognised as a member of the EnprEMA

This document defines 6 criteria with several subcategories (items) for self-assessment. The criteria and their items have been set up in a public process. Minimum criteria were defined that networks should fulfil to be recognised as a member of the EnprEMA. The defined minimum criteria are flagged with a superscript "**M**".

Irrespective of whether or not only minimum criteria / items are fulfilled, the full list of the criteria and items as well as the network identification should be completed to the extent possible.

Use of the document and application of the recognition criteria

The criteria should be reported for the highest level that the network currently attains. Networks should report on the status of the network, not on individual investigators or sites. For the purpose of this document, the highest level is called the reporting party.

The document should be filled in by the reporting party (once only per network), taking into account the guidance text provided for the various items within the respective criterion. For transparency in general and to permit public scrutiny of the self-assessment, the completed document should be made public by the reporting party, for example, on their website.

For the same purpose, the reporting party should also make publicly accessible the actual data on which the statements are based. For example, if numbers of paediatric trials are provided, references to clinical trial registration numbers could be made publicly accessible.

The self-assessment should be updated annually.

This document should be sent to the European Medicines Agency; it will be published on the EMA webpage.

Criteria for the recognition of an investigator, site* or network as a member of the EnprEMA*

* only when the investigator or the site is not part of a network

Identification M

Name	EUNETHYDIS (the European Network for Hyperkinetic Disorders). Stichting Eunethydis Foundation, Ign. Bispincklaan 11, 2061 EM Bloemendaal, The Netherlands.	Include legal address, define acronyms
Type	Speciality Network. Eunethydis is primarily concerned with the study of ADHD from a clinical and fundamental research point of view and provides research Guidelines. EUNETHYDIS also supports the development and implimentation of clinical research in other areas of child mental health research including paediatric psychopharmacology.	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	Ign. Bispincklnaan 11	
Postal code	2061 EM	
Town	Bloemendaal	
Country	The Netherlands	
Telephone 1	+31 23 525 8428	
Telephone 2		
Mobile phone	+31 6 218 780 72	
Fax	+31 23 526 8453	
Web site	Under construction.	If available (see criterion 4)
Email for general enquiries	josephasergeant@gmail.com	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Professor Joseph	
Second name	Sergeant	
Telephone	+31 23 525 8428	
Mobile phone	+31 6 218 780 72	
Email	josephasergeant@gmail.com	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	David Prof. Dr.	

Second name	Coghill	
Telephone	+441382204004	
Mobile phone	+447710436544	
Email	d.r.coghill@dundee.ac.uk	
The data in this document are 'current' as of	September 2nd 2010	Provide the date when the criteria were last updated
State how this document can be accessed by the public	Until our web site is completed via: josephasergeant@gmail.com	This should be a link to a webpage, but other means and formats to make public are possible

Description M

Year of foundation	1989	Of the network, or of the investigator's or site's specific paediatric research activities
Paediatric age ranges of study participants covered by the network		
Preterm and / or term newborn	☐ Yes ☒ No	Newborn: from birth to less than 28 days of age
Infants from 1 month to less 24 months of age	☐ Yes ☒ No	
Children from 2 years to less than 12 years of age	☒ Yes ☐ No	
Adolescents from 12 years to less than 18 years	☒ Yes ☐ No	
Specialities / Conditions covered	Child Psychiatry, Child Clinical Psychology, Child Neuropsychology, Child Neurology, Child Psychiatric Epidemiology, Developmental Neuroscience, Developmental Pharmacology.	ENPREMA will cover a range of different networks, from single speciality trials groups to those covering all paediatrics. If not all areas within one speciality are covered, specify conditions
Multispeciality? Specify	Yes: Psychiatry, Psychology, Neurology, Neuroscience, Molecular Genetics, Neuropharmacology.	For example, oncology or infectious diseases
Speciality or disease specific? Specify	Disease specific: Child and Adolescent mental health with a primary focus on Attention Deficit Hyperactivity Disorder (ADHD) and its comorbidities.	For example, cardiology only
Conditions covered? Specify	ADHD, Autism, Oppositional Deficant Disorder, Conduct Disorder, Dyslexia, Developmental Coordination Disorder, Anxiety, Depression.	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)

Procedure / intervention specific? Specify	Pharmcology, Psychotherapies (including Behavioural Therapy, Family Therapy), Neurofeedback, Dietry Interventions.	For example, surgery, organ or stem cell transplantation
Number of collaborating countries	12 List all collaborating countries: Europe: Belgium, Denmark, France, Germany, Holland, Hungary, Italy, Norway, Spain, Sweden, Switzerland, UK.	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe)
Number of collaborating centres	19 Major Collaborating Centres. List all collaborating centres: See Attachment.	State the number of collaborating centres and provide a list of all collaborating centres (attachment or link possible)
Type of activity/studies		
Clinical studies	☒ Yes ☐ No	
Experimental research	☒ Yes ☐ No	
Other activity	Development of Clinical Guidelines for Practitioners. Monitoring Clinical Practice (e.g. ADORE, a large 2 year European Observational study of ADHD care). Pharmacovigilance (e.g. ADDUCE [Attention Deficit Hyperactivity Disorder Drugs Use Chronic Effects] an EU - FP7 pharmacovigilence study of methylphenidate). Neuroscientific research (includes neuroimaging, neurophysiological and neuropsychological studies many of which are linked to psychopharmacological designs). Molecular Genetics.	Describe type of activities other than clinical and/or non-clinical studies

Evidence for each criterion

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How to provide evidence

1. The evidence for this self-assessment document should be based only on the activity of the network during in the last 5 years.
2. Evidence used in this document should have a reference (e.g., publication, annual or periodic report or internal network document).
3. The self-assessment document is to cover a range of different network types. It is recognised that some networks may not be able to accurately respond to every item. In such circumstances, state why it is not possible to respond.
4. The network is referred to as the "reporting party".

Criterion 1: Research experience and ability

Do not include planned trials, but only ongoing and completed trials.

1.1 Number of completed trials [M] Number of ongoing trials [M]	Completed: 70 - see attached reference list for published studies. 9 completed studies are awaiting publication. Initial studies were completed independently by members at their own sites. However, over the past 5 years sites have collaborated on several large international multicentre trials. Ongoing: 24 This includes 3 EU FP7 funded projects, each of which contains several studies: PERS (Paediatric European Risperidone Studies), STOP (Suicidality: Treatment Occurring in Paediatrics) and ADDUCE.	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.
1.2 Total number of participants actually recruited each year Proportion of eligible participants actually recruited each year Describe way of screening and participant recruitment	> 400 across all studies. Not possible to calculate due to diversity of studies. This varies from trial to trial however all listed members have access to extensive clinical populations within their own centres. There is also a developing network of additional clinical centres with a close connection to the network. Recruitment is usually conducted directly through the clinical centres with screening conducted by clinician researchers working across the research/clinical interface.	Relevant to speciality specific networks. State total recruitment capacity for any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Which strategies or pathways are used to screen and recruit participants?
1.3 Total number of collaborating centres	> 40	For completed and ongoing (open) paediatric trials. Do not include sites in set-up.

Academic (investigator) initiated studies	---	Studies conducted independently from pharmaceutical companies (no sponsorship and no funding). There is a separate category (below) for industry-funded studies.
1.4 Number of ongoing and completed clinical trials	Absolute number: Completed: 37 Ongoing 15 Proportion of all studies: 60%	Paediatric interventional trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation by regulatory authority) (for other Paediatric trials unrelated to drug development see below)
1.5 Number of paediatric specialities covered by paediatric trials	1 (Child and Adolescent Mental Health)	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	6 ADHD, CD, Depression, Schizophrenia, Bipolar, Autism.	If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials
1.7 Number of other ongoing research studies / programs	> 150 All sites are involved in range of other studies. These include epidemiological, observational, basic science, translational, clinical neuroscience, pharmacovigalence and pharmacoepidemiology.	For example, epidemiological studies, outcome studies, translational research in which the reporting party is participating Include cohort studies but not audits. Research is defined as a project with a specific research question in which the participant/family provides formal consent.
1.8 Indicate the proportion of public funding	Proportion of academic initiated studies: Trials: 15 Other studies 150 Proportion of budget: proportion of clinical trials budget 60%.	Indicate the proportion of the budget handled for completed and ongoing paediatric trials that is derived from public funding sources such as governmental programs, competitive public grants, university contributions

1.9 Number of registered study participants (all studies)	In clinical trials 250 In all studies > 5000	
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	Completed: 33 Ongoing: 9	Paediatric interventional trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation)
1.11 Number of paediatric specialities covered by paediatric trials	1 Child and Adolescent Mental Health.	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials	5 ADHD, Depression, Schizophrenia, Conduct disorder, Autism.	If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials
1.13 Number of registered study participants (all studies)	200	

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: Prof. Dr. J.A. Sergeant, Chairman Eunethydis josephasergeant@gmail.com	Enquiries from patients, parents, organisations, researchers, pharma-ceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above.
2.2 Existence of an internal steering committee [M]	☒ Yes ☐ No Comments: Internal steering committee: Prof. J. Sergeant, Dr. D. Coghill, Prof. E. Taylor, Prof. T. Banaschewski, Prof. A. Zuddas, Prof. E. Sonuga-Barke, Prof. M. Holtmann, Prof. C. Soutullo, Prof. T. Sagvolden, Dr. H. Guerts, Dr. A. Stringaris, Dr. S. Cortese.	Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).
2.3 Existence of an external advisory / steering committee directing the reporting party [M]	☐ Yes ☒ No Comments:	Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).
2.4 Existence of a website	☐ Yes ☒ No Comments: Under construction.	If available, mention in "identification" above
2.5 Existence of newsletter	☐ Yes ☒ No Comments: All network communications are published in scientific journals.	Newsletter of any format (electronic, surface mail), distributed actively to selected recipients.

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: Prof. Dr. J.A. Sergeant, Chairman Eunethydis josephasergeant@gmail.com	Enquiries from patients, parents, organisations, researchers, pharma-ceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above.
2.6 Existence of an internal database(s) for disease, condition, treatment and / or outcome [M] If yes, please describe	☐ Yes ☒ No Comments / description: Due to privacy issues internal data bases/disease registries are located at each of the participating clinics. There are also cross site databases of of genetic data that have arisen as a consequence of specific projects. Through Prof. I. Wong the network has access to a range of pharmacoepidemiological databases and through extrenal collaborations we are able to access to several other large long term prospective databases as required for specific projects.	For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data)
2.7 Provisions to ascertain data protection and data security [M]	☒ Yes ☐ No Comments: All databases comply with national and international standards for data protection.	Are provisions in place to ascertain patients' /study participants' data protection and data safety within network
2.8 Procedure(s) to access the database by third parties	☒ Yes ☐ No Comments: All database comply with national and international standards for allowing access to third parties as appropriate.	Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)?

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: Prof. Dr. J.A. Sergeant, Chairman Eunethydis josephasergeant@gmail.com	Enquiries from patients, parents, organisations, researchers, pharma-ceutical companies or regulatory authorities are co-ordinated or answered by a nominated contact person. Provide contact details in section "Identification" above.
2.9 Access to external databases /registries	☒ Yes ☐ No Comments: As noted in 2.6, members of the network have, through their research collaborations, privileged access to a broad range of large research databases not usually accessible to the public. In addition, the network has access to several large national and international pharmacoepidemiological and pharmacovigilence databases. The Network is in discussion with the EMA to be a pilot site for accessing their pharmacovigilence database. In addition we have a long history of collaborative work with industry partners which includes participation in data mining panels and assisting with the design and implementation of data mining projects of large clinical trials datasets.	For example, national databases that are not publicly accessible but to which the reporting party has open or privileged access; database(s) immediately relevant to area and / or scope
2.10 Standardised process to access an external database(s)	☒ Yes ☐ No Comments: Due to the wide range of databases used in various projects and the very different requirements set out by the owners of these data these are negotiated and defined as required.	Is a standardised process in place to access external/ national databases?

Criterion 3: Scientific competencies and capacity to provide expert advice

3.1 Number of peer-reviewed publications in the last 5 years Provide exact reference(s) Describe the network's contribution to publication(s)	Total 735 of which 123 are directly related to the network. See enclosed. For those publications attributed to the network, the networks members directly collaborated on designing and conducting the study, analysing the data and / or contributing to the writing of the paper	The publications should indicate that they are related to and reference the reporting party.
3.2 Number of competitive grants obtained in the last 5 years	Aproximately 20 as a network (members have obtained > 150 grants individually) This includes 1 NIMH (US) grant for an international genetics study and 3 FP7 programme grants (PERS, ADDUCE, STOP) for which summaries are attached.	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups M	☒ Yes ☐ No Comments: Various National Child Psychiatry, Neurology, Psychology Bodies (e.g. Royal College of Psychiatrists, American Academy of Child and Adolescent Psychiatry, German Society of Child and Adolescent Psychiatry, German Society of Clinical Neurophysiology etc), European College of Neuropsychopharmacology, British Association of Psychopharmacology, British Medical Association, UK National Institute for Health and Clinical Excellence.	Indicate if the reporting party has specific access to established expert groups, such as learned societies

3.4 Capacity to answer external scientific questions [M]	☒ Yes ☐ No Comments: Members are frequently called on by industry, regulators, government bodies to answer scientific questions about a wide range of trial related and non-trial related subjects. Members have worked in both industry and academic settings.	Indicate if coordinated capacity (staff, process) is available to answer external scientific questions in relation to clinical trials during daily business.
Standardized procedures for assessment of:	---	
3.5 Site feasibility	☒ Yes ☐ No Comments: Until recently many studies were single site or industry sponsored where this was generally conducted by external bodies. However, with the recent EU awards the network has developed the skills to assess sites for suitability for a given trial. Standardised procedures are being developed across these studies.	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments: All sites have a wealth of experience in recruiting and monitoring. recruitement.	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: See 3.5	This concerns, for example, quotes and prospective financial planning for a trial.

Criterion 4: Quality management

4.1 Documented adherence to Good Clinical Practice (GCP) guideline [M]	☒ Yes ☐ No Comments: All trials are designed to comply with EU directive 2001/20/EC on clinical trials. Compliance is monitored and no significant problems have arisen when audits have been conducted.	Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.
4.2 Documented adherence to the ethical considerations for clinical trials in children [M]	☒ Yes ☐ No Comments: All projects are passed by local/national ethical bodies and comply with the special ethical requirements for paediatric trials.	Indicate if documented data / information are publicly available on implementation of / provisions for special ethical requirements for the paediatric trial(s) according to the document "Ethical considerations for clinical trials on medicinal products conducted with the paediatric population".
4.3 Documented adherence to ethical considerations	☒ Yes ☐ No Comments: All projects met Ethical Committee approval.	Declare whether reporting party requests approval by an independent ethics committee with paediatric expertise for all studies conducted.
4.4 Availability of Standard Operation Procedures (SOP)	☒ Yes ☐ No If yes, provide reference to available SOPs See 3.5 In the past most sites determined their own SOPs for single site trials or used those determined by industry sponsors. For the FP7 studies the network is collaborating with the University of Dundee/NHS Tayside Clinical trials Unit and will adopt their SOPs where available and collaborate with them in the development/adoption of new SOPs where required.	Indicate existence of SOP e.g. for study management, adverse events reporting etc.

4.5 Capacity to monitor studies (academic trials, industry sponsored trials) M	☒ Yes ☐ No Comments: All trials adhere to the monitoring of trials as determined by ICH GCP.	Indicate if the reporting party implements the monitoring of paediatric trials according to ICH 6 Good Clinical Practice Guideline.
4.6 Capacity to monitor performance of collaborating centres	☒ Yes ☐ No Comments: There is a lead site for each project who takes responsibility for implementing monitoring of performance either through a clinical trials unit or via an external CRO.	Indicate if the reporting party implements the monitoring of performance of collaborating centres.
4.7 Quality control and quality assurance, traceability and data safety M	☒ Yes ☐ No Comments: as in 4.6	Indicate if this is implemented in the reporting party's remit.

Criterion 5: Training and educational capacity to build competences

5.1 Evidence of collaboration with regulatory authorities [M]	☒ Yes ☐ No Comments: Several members have had extensive experience contributing to and collaborating with regulatory authorities e.g. Prof. E. Taylor, UK MHRA, Prof. A. Zuddas, Italian ADHD Registry and Italian Regulatory Authority, Profs. Buitelaar & Sergeant, Advisors: Dutch Ministry of Health on ADHD, Prof. I. Wong, UK MHRA.	Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.
5.2 Capacity to provide competent consultation to regulatory authorities	☒ Yes ☐ No Comments: See 5.1	Indicate the capacity of the reporting party to provide expert advice to regulatory authorities. For example, nominations into standing scientific committees to regulatory authorities, registration(s) as authorities' external expert(s).
5.3 Formal meetings for clinical trials If yes, provide number	☒ Yes ☐ No Comments: 10-15 per year for various trials, these include planning meetings for PIs, investigator meetings, training meetings for site staff, ongoing meetings regarding recruitment, rater reliability etc.	For example, investigator meetings, trainings specific to a given ongoing or planned trial.
5.4 Training courses given over the last 2 years [M] If yes, provide number	☒ Yes ☐ No Comments: Network members have provided trial specific training for both industry sponsored and publicly funded academci trials (e.g. PERS).	For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party. Minimum requirement (M): training courses either given (5.4) or received (5.5).

5.5 Training courses received over the last 2 years [M] If yes, provide number	☒ Yes ☐ No Comments: Network members have also received trial specific training for a range of industry sponsored trials. Network members also complete specific ICH GCP training course on a regular basis.	For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party. Minimum requirement (M): training courses either given (5.4) or received (5.5).
5.6 Promotion of participation in clinical trials in countries with limited resources Provide list of countries	☒ Yes ☐ No Comments: The network has involved several countries with limited resources in clinical trials and has encouraged industry partners to include such countries in their ADHD studies. Hungary, Poland, Portugal.	Indicate if support for such trials is provided by the reporting party.

Criterion 6: Public involvement M

Minimum requirement (M): involvement in at least one of the below items.

6.1 Involvement of patients, parents or their organisations in the protocol design	☐ Yes ☒ No Comments:	Indicate if public stakeholders are /have been involved
6.2 Involvement of patients, parents or their organisations in creating the protocol information package	☒ Yes ☐ No Comments: Several national parent ADHD organizations have been involved in developing patient information packages.	Indicate if public stakeholders are /have been involved
6.3 Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children	☒ Yes ☐ No Comments: Parental organizations provided information in gaining national support for improved clinical services and lobbying for increased funding for both pharmacological and non-pharmacological clinical trials in ADHD.	Indicate if public stakeholders are /have been involved