EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2011
EMA/153678/2011
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 Emprema@ema.europa.eu

END OF SELF-ASSESSMENT PERIOD	31 July 2010

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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	**Red SAMID**	**Include legal address, define acronyms**
Type	Spanish National Obstetric and Paediatric Research Network	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	Plaza de Cruces s/n	
Postal code	48903	
Town	Barakaldo	
Country	Spain	
Telephone 1	+34 94 600 6394	
Telephone 2	+34 94 600 2305	
Mobile phone	+34 699977831	
Fax	+34 600 60 76	
Web site	www.redsamid.net	If available (see criterion 4)
Email for general enquiries	gestor.euroneonet@euskalnet.net	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Adolf	
Second name	Valls-i-Soler	
Telephone	+34 600 6394	
Mobile phone	+34 699977831	
Email	enadolf@gmail.com	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Aitor	
Second name	Tenería	
Telephone	+34 94 600 63 28	
Mobile phone		
Email	gestor.samid@euskalnet.net	
The data in this document are 'current' as of	20/02/2012	Provide the date when the criteria were last updated
State how this document can be accessed by the public	www.redsamid.net	This should be a link to a webpage, but other means and formats to make public are possible

Description M

Year of foundation	**2008**	**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	Fetal and neonatal conditions, mainly intrauterine growth restriction and asphyxia, other conditions related to prematurity (ductus, IVH) are also covered. Area _____ methabolic risk in obesity, hypertension and type II diabetes are covered too.	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	Paediatrics, obstetrics, matabolism, intesive care and paediatric surgery	For example, oncology or infectious diseases
Speciality or disease specific? Specify		For example, cardiology only
Conditions covered? Specify		E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify	Intensive care, surgery	For example, surgery, organ or stem cell transplantation
Number of collaborating countries	one List all collaborating countries: spain	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe)
Number of collaborating centres	13 research groups and 21 associated centers List all collaborating centres: http://www.redsamid.net/?q=node/74 http://www.redsamid.net/?q=node/75	State the number of collaborating centres and provide a list of all collaborating centres (attachment or link possible)

Year of foundation	**2008**	**Of the network, or of the investigator's or site's specific paediatric research activities**
Type of activity/studies		
Clinical studies	☒ Yes ☐ No	
Experimental research	☒ Yes ☐ No	
Other activity	randomised clinical trials	Describe type of activities other than clinical and/or non-clinical studies

Evidence for each criterion

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]	**one "PESARIO" (Completed)(Goya M, Pratcorona L, Merced C, Rodo C, Valle L, Romero A, et al. Cervical pessary in pregnant women with a short cervix (PECEP): an open-label randomised controlled trial. Lancet. 2012;379:1800-1806** **five** **1.Topiramato (2011-005717-36)** **2.PRESOX (** **3.Safebooth (2011-005696-17)** **4.Heparina de bajo peso molecular** **(2010-023597-39)** **5. Metformina (2010-023061-21)**	**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	50 centers. more than 500 children of 80 % different ages Network has contact with units. having previous knowledge of its capacity	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	25	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	Absolute number: 7	Paediatric interventional trials of any phase of the

1.1 **Number of completed trials** [M] **Number of ongoing trials** [M]	**one "PESARIO" (Completed)(Goya M, Pratcorona L, Merced C, Rodo C, Valle L, Romero A, et al. Cervical pessary in pregnant women with a short cervix (PECEP): an open-label randomised controlled trial. Lancet. 2012;379:1800-1806** **five** **1.Topiramato (2011-005717-36)** **2.PRESOX (** **3.Safebooth (2011-005696-17)** **4.Heparina de bajo peso molecular** **(2010-023597-39)** **5. Metformina (2010-023061-21)**	**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.**
completed clinical trials	Proportion of all studies: 50%	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	four	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	six	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	Epidemiolofical Studies: CANDINEO Cohort Studies: RNMBP Fentanilo (Dynakin)	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

1.1 **Number of completed trials** [M] **Number of ongoing trials** [M]	**one "PESARIO" (Completed)(Goya M, Pratcorona L, Merced C, Rodo C, Valle L, Romero A, et al. Cervical pessary in pregnant women with a short cervix (PECEP): an open-label randomised controlled trial. Lancet. 2012;379:1800-1806** **five** **1.Topiramato (2011-005717-36)** **2.PRESOX (** **3.Safebooth (2011-005696-17)** **4.Heparina de bajo peso molecular** **(2010-023597-39)** **5. Metformina (2010-023061-21)**	**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.**
		provides formal consent.
1.8 Indicate the proportion of public funding	Proportion of academic initiated studies: 90% Proportion of budget: 70%	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)		
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials		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		Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials		If not all areas within one speciality covered count conditions, without repetition, across all

1.1 **Number of completed trials** [M] **Number of ongoing trials** [M]	**one "PESARIO" (Completed)(Goya M, Pratcorona L, Merced C, Rodo C, Valle L, Romero A, et al. Cervical pessary in pregnant women with a short cervix (PECEP): an open-label randomised controlled trial. Lancet. 2012;379:1800-1806** **five** **1.Topiramato (2011-005717-36)** **2.PRESOX (** **3.Safebooth (2011-005696-17)** **4.Heparina de bajo peso molecular** **(2010-023597-39)** **5. Metformina (2010-023061-21)**	**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.**
		ongoing or completed paediatric trials
1.13 Number of registered study participants (all studies)		

Criterion 2: Network organisation and processes

2.1 **Existence of an identified contact person for external enquiries** [M]	☒ **Yes** ☐ **No** **Comments:** **Adolf Valls-i-Soler, Project Leader and coordinator** **Aitor Teneria Yañez, Project manager**	**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: six key members 1.Adolf Valls-i-Soler 2.Fernando Cabañas 3.Máximo Vento 4. Luis Cabero 5. Jesús López Herce 6. Luis Moreno Aznar	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: Eduardo Bancalari (University of Florida) Waldemar Carlo-Pont (University of Alabama) Robert Gondenberg (Drexel University) Philadelfia Julio Perez Fontan (Southwester Medical School, Dallas) Ricardo Uauy (Universidad de Chile) Eduardo Villamor Zambrano (Maastricht, Holland)	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: www.redsamid.net	If available, mention in "identification" above
2.5 Existence of newsletter	☒ Yes ☐ No Comments: www.redsamid.net	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:** **Adolf Valls-i-Soler, Project Leader and coordinator** **Aitor Teneria Yañez, Project manager**	**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: for VLBW infants: information on perinatal risk factors, neonatal interventions and short and long term outcomes	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: Data is submitted to the central office anonymously for patient and unit identities. Unique code and encrypted database are used. the database items, definitions and all protection and security precesses were possitibly evaluated by http://www.agpd.es/portalwebAGPD/index-ides-idphp.php Mirror Servers are used	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:	Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)?
2.9 Access to external databases /registries	☐ Yes ☒ No Comments:	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:	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)**	**22** **Pediatr Crit Care med 2012;13:1-10** **Journal of Hospital Infection 2012;81:123-127** **J Aerosol Med Pulm Drug Deliv 2012;25:23-31** **Pediatr Crit Care Med. 2012;13:187-194** **Arch Dis Child 2012, 97:185-188** **Frontiers in Neuroscience 2011;5:1-12** **Pediatr Pulmonol 2011;46:991-999** **Neonatology 2011;100:71-77** **Will provide the rest of the reference if needed** **Helped in design and recruitment**	**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	Red SAMID (Granted by the Spanish Ministry of Health) Red SAMID II (pending)	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups M	☒ Yes ☐ No Comments: Spanish Obstetrical Neonatal and paediatrics Societies	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: the network has the capacity to answer external scientidic question related to RCT. the staff of the coordinating office tranfers the question to the more appropiate researchers of the network.	Indicate if coordinated capacity (staff, process) is available to answer external scientific questions in relation to clinical trials during daily business.

3.1 **Number of peer-reviewed publications in the last 5 years** **Provide exact reference(s)** **Describe the network's contribution to publication(s)**	**22** **Pediatr Crit Care med 2012;13:1-10** **Journal of Hospital Infection 2012;81:123-127** **J Aerosol Med Pulm Drug Deliv 2012;25:23-31** **Pediatr Crit Care Med. 2012;13:187-194** **Arch Dis Child 2012, 97:185-188** **Frontiers in Neuroscience 2011;5:1-12** **Pediatr Pulmonol 2011;46:991-999** **Neonatology 2011;100:71-77** **Will provide the rest of the reference if needed** **Helped in design and recruitment**	**The publications should indicate that they are related to and reference the reporting party.**
Standardized procedures for assessment of:	---	
3.5 Site feasibility	☒ Yes ☐ No Comments: Coordinating center	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments: Coordinating center	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: Coordinating Center	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:** **we declare that all studies being conducted do comply with the EU directive 2001/20/EC on Clinical Trials**	**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: Documented information is publicly available on our website about oour adherence to both, the ethical considerations for randomized clinical trial of the EMA (EMA/146065/2012) and to the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the WHO	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:	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	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: Trial monitoring	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:	Indicate if the reporting party implements the monitoring of performance of collaborating centres.

4.1 **Documented adherence to Good Clinical Practice (GCP) guideline** M	☒ **Yes** ☐ **No** **Comments:** **we declare that all studies being conducted do comply with the EU directive 2001/20/EC on Clinical Trials**	**Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.**
4.7 Quality control and quality assurance, traceability and data safety M	☒ Yes ☐ No Comments: Specific standarised processes for Quality Control & Quality Assurance are available Data quality check is done at data entry, using a code, checking for missing values, outliers, discrepancies/incoherence to notify units. A random 5% of datasets is double-checked.. Traceability for both patient and unit identity is prevented by use of a unique coding system All data introduce in the database is secure by a double "servidor en espejo" get by SARENET (http://www.sarenet.es/SARENET/portada.htm) Unique code and encrypted databases, MIrrors servers are used	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:** **Collaboration (EnprEMA, GRIP, AEMPS)**	**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:	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: Two a year, one for each specific trial	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: two INTERNATIONAL WORKSHOP ON PAEDIATRIC CLINICAL TRIALS (Thursday, September 22th, 2011) II INTERNATIONAL WORKSHOP ON PAEDIATRIC CLINICAL TRIALS (Wednesday, November 21st, 2012)	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: six	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).

5.1 **Evidence of collaboration with regulatory authorities** M	☒ **Yes** ☐ **No** **Comments:** **Collaboration (EnprEMA, GRIP, AEMPS)**	**Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.**
5.6 Promotion of participation in clinical trials in countries with limited resources Provide list of countries	☐ Yes ☒ No Comments:	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:** **Association of parents of premature infants (APREVAS, EFCNI)**	**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: The EFCNI organisation is involved on the EuroNeoKiss trial, funding in which has been seek by applying to the CER call on Health by the 7th RFW program	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:	Indicate if public stakeholders are /have been involved