8 May 2012
EMA/817617/2010
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	FIMP - MCRN (Italian Paediatric Federation- Medicines for Children Research Network) [ANNEX n.1] http://www.ijponline.net/content/36/1/46 Legal address: Via Carlo Bartolomeo Piazza,n.30 - Roma 00161- Italy	Include legal address, define acronyms

Name	FIMP - MCRN (Italian Paediatric Federation- Medicines for Children Research Network) [ANNEX n.1] http://www.ijponline.net/content/36/1/46 Legal address: Via Carlo Bartolomeo Piazza,n.30 - Roma 00161- Italy	Include legal address, define acronyms
Type	National, transversal Network, representing community paediatricians/primary care physicians. It has been created to improve international standards of ethics and scientific quality by means of an agreement between individuals co-operating for the same objectives, goals and quality standards. More than 6000 Italian Family Paediatricians are involved from 20 Italian Regions (every Italian Region is coordinated by a Regional Referent), covering the entire Italian territory. Since every paediatrician takes care of 900 children and follows them from their birth to 14 years of age, the FIMP-MCRN can survey more than 6.000.000 Italian children. Family Paediatricians (FP) are an important reference for those families with which they establish a strong and long lasting relationship based on trust. The FIMP - MCRN have developed and improved its expertise in Phase 3 and 4 clinical trials (Ministerial Decree n.139/2001) : observational and epidemiological studies; long term follow up (LTFU) clinical studies; efficacy studies (DBPC-RCT and/or comparative treatment studies); safety studies (Post-marketing , Pharmacovigilance) Objectives:1)To build competences (Training and educational) 2) Infrastructure and organization 3) Quality and ethicality - clinical trials 4) Better communication with families and disease-patients associations 5) Better medicines for children 6) To identify Pediatric Health Care Problems [ANNEX n.2]	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement

Name	FIMP - MCRN (Italian Paediatric Federation- Medicines for Children Research Network) [ANNEX n.1] http://www.ijponline.net/content/36/1/46 Legal address: Via Carlo Bartolomeo Piazza,n.30 - Roma 00161- Italy	Include legal address, define acronyms
Street	Via Carlo Bartolomeo Piazza ,n. 30	
Postal code	00161	
Town	Roma	
Country	Italy	
Telephone 1	+39 644202575	
Telephone 2		
Mobile phone		
Fax		
Web site	www.fimp.org/sperimentazione	If available (see criterion 4)
Email for general enquiries	ricerca.sperimentazione@fimp.org	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Ettore	
Second name	Napoleone	
Telephone	+39874415339	
Mobile phone	3295969376	
Email	ettorenapoleone@tiscali.it	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Giuseppe	
Second name	Mele	
Telephone	+39832.347808	
Mobile phone	335.1445739	
Email	presidenza@fimp.org	
The data in this document are 'current' as of	02/03/2012	Provide the date when the criteria were last updated
State how this document can be accessed by the public	25th july 2010	This should be a link to a webpage, but other means and formats to make public are possible

Description M

Year of foundation	The FIMP-MCRN was established in 2003 with the aim of developing competence, infrastructure, networking and education for paediatric clinical trials. Since 2003, the year FIMP-MCRN was founded, Family Paediatricians have participated to various clinical studies and research projects in collaboration with the most important national Universities and/or Research Institutes. This has allowed them to acquire experience and rigorous methodology in clinical paediatrics research. Despite the fact that in the opening phases, Family Paediatrician involvement in clinical trials was quite poor throughout the Italian territory, from 2008 a national organisation has created the characteristics for a fully independent scientific running of clinical trials.	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	All the specialities	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	Infectious and respiratory disease ,allergology,vaccinology, nutrition, phytotherapy, dermatology, gastroenterology	For example, oncology or infectious diseases

Year of foundation	The FIMP-MCRN was established in 2003 with the aim of developing competence, infrastructure, networking and education for paediatric clinical trials. Since 2003, the year FIMP-MCRN was founded, Family Paediatricians have participated to various clinical studies and research projects in collaboration with the most important national Universities and/or Research Institutes. This has allowed them to acquire experience and rigorous methodology in clinical paediatrics research. Despite the fact that in the opening phases, Family Paediatrician involvement in clinical trials was quite poor throughout the Italian territory, from 2008 a national organisation has created the characteristics for a fully independent scientific running of clinical trials.	Of the network, or of the investigator's or site's specific paediatric research activities
Speciality or disease specific? Specify	vaccines,gastroenterology,etc	For example, cardiology only
Conditions covered? Specify	otitis, asthma,pharyngotonsillitis (FT) and rhinosinusitis (RS)	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify		For example, surgery, organ or stem cell transplantation
Number of collaborating countries	1 List all collaborating countries:	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe)
Number of collaborating centres	22 List all collaborating centres: [ANNEX n.3]	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	

Year of foundation	The FIMP-MCRN was established in 2003 with the aim of developing competence, infrastructure, networking and education for paediatric clinical trials. Since 2003, the year FIMP-MCRN was founded, Family Paediatricians have participated to various clinical studies and research projects in collaboration with the most important national Universities and/or Research Institutes. This has allowed them to acquire experience and rigorous methodology in clinical paediatrics research. Despite the fact that in the opening phases, Family Paediatrician involvement in clinical trials was quite poor throughout the Italian territory, from 2008 a national organisation has created the characteristics for a fully independent scientific running of clinical trials.	Of the network, or of the investigator's or site's specific paediatric research activities
Other activity	- Training and educational - National and international meetings -Workshops organisation - External enquires (from patients,parents,organisation, researchers,pharmaceutical companies , regulatory authorities) -Disease registry and national survey	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]	From 2008: n.1 completed trials From 2009 : n. 2 ongoing trials	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	In 2008 537 children were recruited In 2009 about 600 children were recruited The FIMP-MCRN can survey more than 6.000.000 Italian children.The merit of FP is their close elective involvement with children and their families. In Italy, a FP generally establishes a very strong and close "pediatrician-parents" and "pediatrician-child" relationship.For this reason it become easier the capacity to assess and involve outpatients in clinical trials. Practical reasons:1) Numbers of patients;2)FP as a member of the family;3) Direct relationship with the children;4) Presence of territorial pathologies;5) Frequency of the contacts out-patient both in ambulatory and domiciliary : Importance of the communication. 1)Explain in simple way, easily comprehensible and with sincerity; 2) Reassurance on:importance of the benefits,risks minimisation; experience of the pediatricians; the policy privacy;the protection of the data;3) Correct information and family consent ;4) Correct Information and Children Assent	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?

1.1 Number of completed trials [M] Number of ongoing trials [M]	From 2008: n.1 completed trials From 2009 : n. 2 ongoing trials	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.
1.3 Total number of collaborating centres	-	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: 3 Proportion of all studies: Completed clinical study: 1 Ongoing clinical trials : 2	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	3	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	3	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	N.1 EPIDEMIOLOGICAL SURVEY ON OBSERVED ACUTE OTITIS MEDIA IN A PEDIATRIC POPULATION	For example, epidemiological studies, outcome studies,

1.1 Number of completed trials [M] Number of ongoing trials [M]	From 2008: n.1 completed trials From 2009 : n. 2 ongoing trials	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.
		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: The budget handled for complete and ongoing trials is derived from FIMP funding sources Proportion of budget:	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)	1	
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	0	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 ongoing or completed

1.1 Number of completed trials [M] Number of ongoing trials [M]	From 2008: n.1 completed trials From 2009 : n. 2 ongoing trials	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.
		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: All external enquires (from patients,parents,organisation, researchers,pharmaceutical commpanies , regulatory authorities) are coordinated by Dr.Ettore Napoleone ,Head of FIMP-MCRN and Dr.G.Mele ,FIMP President. Dr.Napoleone is member of AIFA (Italian Drug Agency) Paediatric Working Group and member of ASREM Ethics Committee	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: Steering Committee inside the FIMP, formed by family paediatricians who have the best competence and experience. The Steering Committee, with the responsibility and supervision of the Head of FIMP-MCRN, will have the task of proposing research projects, regular reviewing, organising training courses, epidemiological investigating, attending to international conferences, magazine publishing with IF and everything which has to do with science and that will be considered useful for family paediatricians' clinical research. Moreover, the Steering Committee will control, verify and implement all the scientific activities proposed and/or suggested by each member of the RWG. Finally, the Steering Committee will have the task to verify the methodological quality of all the research projects which will then be evaluated by Ethics Committees.	Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: All external enquires (from patients,parents,organisation, researchers,pharmaceutical commpanies , regulatory authorities) are coordinated by Dr.Ettore Napoleone ,Head of FIMP-MCRN and Dr.G.Mele ,FIMP President. Dr.Napoleone is member of AIFA (Italian Drug Agency) Paediatric Working Group and member of ASREM Ethics Committee	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.
2.3 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: www.fimp.org (FIMP website) www.fimp.org/sperimentazione (FIMP-MCRN website)	If available, mention in "identification" above
2.5 Existence of newsletter	☒ Yes ☐ No Comments: Newsletter are distributed actively both on website and on surface mail to unclosed recipients	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: All external enquires (from patients,parents,organisation, researchers,pharmaceutical commpanies , regulatory authorities) are coordinated by Dr.Ettore Napoleone ,Head of FIMP-MCRN and Dr.G.Mele ,FIMP President. Dr.Napoleone is member of AIFA (Italian Drug Agency) Paediatric Working Group and member of ASREM Ethics Committee	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: FIMP-MCRN capacity to recruit patients is very high.[e.g.Disease Register -FIMP DUMBO Otitis Study.The study is an epidemiological survey on observed acute otitis media in a Italian pediatric population. The main objective of the project is to create a disease register and to evaluate the incidence of AOM in all children aged between 0 and 59 months in relation to their clinical severity or recurrence. The clinical diagnosis of AOM, according to the recommendations of the AAP, will be supported by a Pneumatic Otoscope. This study is on-going(until now we recuited more than 600 children)]	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: The traceability, the transparency and the safety of data are submitted to an computer engineering company called VAM Srl which has an ISO 27001 Certification. Policy privacy is guaranteed.	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)?

2.1 Existence of an identified contact person for external enquiries M	☒ Yes ☐ No Comments: All external enquires (from patients,parents,organisation, researchers,pharmaceutical commpanies , regulatory authorities) are coordinated by Dr.Ettore Napoleone ,Head of FIMP-MCRN and Dr.G.Mele ,FIMP President. Dr.Napoleone is member of AIFA (Italian Drug Agency) Paediatric Working Group and member of ASREM Ethics Committee	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:	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)	n. 24 (in collaboration with University and/or Research Institutes) n. 5 independent [ANNEX n.4]. Since 2003, the year FIMP-MCRN was founded, Family Paediatricians have participated to various clinical studies and research projects in collaboration with the most important national Universities and/or Research Institutes (Regional network's contribution). This has allowed them to acquire experience and rigorous methodology in clinical paediatrics research. Despite the fact that in the opening phases, Family Paediatrician involvement in clinical trials was quite poor throughout the Italian territory, from 2008 a national organisation has created the characteristics for a fully independent scientific running of clinical trials (National network's contribution).	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	Not grants obtained by reporting party	Grants obtained by reporting party (exclusively or not).

3.1 Number of peer-reviewed publications in the last 5 years Provide exact reference(s) Describe the network's contribution to publication(s)	n. 24 (in collaboration with University and/or Research Institutes) n. 5 independent [ANNEX n.4]. Since 2003, the year FIMP-MCRN was founded, Family Paediatricians have participated to various clinical studies and research projects in collaboration with the most important national Universities and/or Research Institutes (Regional network's contribution). This has allowed them to acquire experience and rigorous methodology in clinical paediatrics research. Despite the fact that in the opening phases, Family Paediatrician involvement in clinical trials was quite poor throughout the Italian territory, from 2008 a national organisation has created the characteristics for a fully independent scientific running of clinical trials (National network's contribution).	The publications should indicate that they are related to and reference the reporting party.
3.3 Access to expert groups M	☒ Yes ☐ No Comments: Reporting party has specific access to: 1) SIP (Italian Society of Paediatrics) 2) SIRP (Italian Society of Paediatric Research) 3) AIFA-PWG (Italian medicines Agency- Paediatric working Group) 4) SIF (Italian Society of Pharmacology) 5) EAP (European Academy of Paediatrics)	Indicate if the reporting party has specific access to established expert groups, such as learned societies

3.1 Number of peer-reviewed publications in the last 5 years Provide exact reference(s) Describe the network's contribution to publication(s)	n. 24 (in collaboration with University and/or Research Institutes) n. 5 independent [ANNEX n.4]. Since 2003, the year FIMP-MCRN was founded, Family Paediatricians have participated to various clinical studies and research projects in collaboration with the most important national Universities and/or Research Institutes (Regional network's contribution). This has allowed them to acquire experience and rigorous methodology in clinical paediatrics research. Despite the fact that in the opening phases, Family Paediatrician involvement in clinical trials was quite poor throughout the Italian territory, from 2008 a national organisation has created the characteristics for a fully independent scientific running of clinical trials (National network's contribution).	The publications should indicate that they are related to and reference the reporting party.
3.4 Capacity to answer external scientific questions M	☒ Yes ☐ No Comments:	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:	---	

3.1 Number of peer-reviewed publications in the last 5 years Provide exact reference(s) Describe the network's contribution to publication(s)	n. 24 (in collaboration with University and/or Research Institutes) n. 5 independent [ANNEX n.4]. Since 2003, the year FIMP-MCRN was founded, Family Paediatricians have participated to various clinical studies and research projects in collaboration with the most important national Universities and/or Research Institutes (Regional network's contribution). This has allowed them to acquire experience and rigorous methodology in clinical paediatrics research. Despite the fact that in the opening phases, Family Paediatrician involvement in clinical trials was quite poor throughout the Italian territory, from 2008 a national organisation has created the characteristics for a fully independent scientific running of clinical trials (National network's contribution).	The publications should indicate that they are related to and reference the reporting party.
3.5 Site feasibility	☒ Yes ☐ No Comments: Family Paediatricians can carry out phase three and four of clinical studies according to the Ministerial Decree 139/2001 which states that clinical trials can be carried out in all those ambulatories, of both single and/or associate doctors, which have all the characteristics (logistics, instrumentations, etc.) in accordance with the protocol of studies and the principles of ICH-GCP;	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments:	This concerns provisions to regularly monitor recruitment progress for a trial.

3.1 Number of peer-reviewed publications in the last 5 years Provide exact reference(s) Describe the network's contribution to publication(s)	n. 24 (in collaboration with University and/or Research Institutes) n. 5 independent [ANNEX n.4]. Since 2003, the year FIMP-MCRN was founded, Family Paediatricians have participated to various clinical studies and research projects in collaboration with the most important national Universities and/or Research Institutes (Regional network's contribution). This has allowed them to acquire experience and rigorous methodology in clinical paediatrics research. Despite the fact that in the opening phases, Family Paediatrician involvement in clinical trials was quite poor throughout the Italian territory, from 2008 a national organisation has created the characteristics for a fully independent scientific running of clinical trials (National network's contribution).	The publications should indicate that they are related to and reference the reporting party.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments:	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: FIMP-MCRN studies are conducted according to ICH 6 GCP guideline,to the indications of the European (2001/20/EC) Directive on Clinical Trials,to the Italian Guideline for the management of clinical investigations in pediatrics (Agency for the Regional Sanitary Services) and to the Ethical Considerations for clinical trials on medicinal products conducted with the paediatric population – EMA 2008 .	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: FIMP-MCRN studies are conducted according to ICH 6 GCP guideline,to the indications of the European (2001/20/EC) Directive on Clinical Trials,to the Italian Guideline for the management of clinical investigations in pediatrics (Agency for the Regional Sanitary Services) and to the Ethical Considerations for clinical trials on medicinal products conducted with the paediatric population – EMA 2008 .	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 the FIMP-MCRN studies request approval by indipendent Ethics Committee with paediatric expertise.	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 FIMP has improved its own standards of operational procedures (SOP), granting the highest levels of control in transparency, safety and quality of data and of submitted studies.	Indicate existence of SOP e.g. for study management, adverse events reporting etc.

4.1 Documented adherence to Good Clinical Practice (GCP) guideline [M]	☒ Yes ☐ No Comments: FIMP-MCRN studies are conducted according to ICH 6 GCP guideline,to the indications of the European (2001/20/EC) Directive on Clinical Trials,to the Italian Guideline for the management of clinical investigations in pediatrics (Agency for the Regional Sanitary Services) and to the Ethical Considerations for clinical trials on medicinal products conducted with the paediatric population – EMA 2008 .	Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.
4.5 Capacity to monitor studies (academic trials, industry sponsored trials) [M]	☒ Yes ☐ No Comments: The FIMP has got a Quality Control System (FPI- Monitor) according to ICH6 Good Clinical Practice Guideline	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: We have the capacity to monitor performance of colaborating centres (e.g. we take part in the Research Monitoring Committee of the study: "Effectiveness of beclomethasone versus placebo for prophylaxis of viral wheezing in preschool" of Mario Negri Institute,Milano).	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: The FIMP has got a Quality Control System (FPI- Monitor) that guarantees the ICH-GCP, a Quality Assurance (FPI- Auditor) which carries out some audits to check the QA as required by the ICH regulations, a Safety Monitoring (control of possible ADRs in clinical trials). The traceability, the transparency and the safety of data are submitted to an computer engineering company called VAM Srl which has an ISO 27001 Certification.	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: Dr Ettore Napoleone is member of PWG -AIFA.PWG was formed with the aim to create continuity between the world of pediatrics and Regulatory activity both Italian and international level (EMA). PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children. PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children.FIMP (AIFA-PWG) contributed to regulatory activities with a critical revision of the benefit/risk profile of some relevant paediatric drugs (e.g. sympathomimetic nasal decongestants banned below 12aa, metocloparamide prohibited below 16aa, recommendations on tropicamide and phenylephrine , domperidone and oxatomide).A systematic analysis was conducted off-label use of medicines for children.It 'was drawn up an updated list of off-label drugs associated with the availability of scientific evidence 29 off-label drugs that are necessary to treat cardiovascular pathologies in children are legitimized by the PWG-AIFA. Thus, their use is authorized and they can be supplied by the National Health Service. Such drugs belong to the following classes: antiarrthymics, calcium antagonists, hypocholesterolemics, hypotensives, peripheral vessel dilators, ACE-inhibitors, beta-blockers, diuretics and sympathicomimetics. .	Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.

5.1 Evidence of collaboration with regulatory authorities M	☒ Yes ☐ No Comments: Dr Ettore Napoleone is member of PWG -AIFA.PWG was formed with the aim to create continuity between the world of pediatrics and Regulatory activity both Italian and international level (EMA). PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children. PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children.FIMP (AIFA-PWG) contributed to regulatory activities with a critical revision of the benefit/risk profile of some relevant paediatric drugs (e.g. sympathomimetic nasal decongestants banned below 12aa, metocloparamide prohibited below 16aa, recommendations on tropicamide and phenylephrine , domperidone and oxatomide).A systematic analysis was conducted off-label use of medicines for children.It 'was drawn up an updated list of off-label drugs associated with the availability of scientific evidence 29 off-label drugs that are necessary to treat cardiovascular pathologies in children are legitimized by the PWG-AIFA. Thus, their use is authorized and they can be supplied by the National Health Service. Such drugs belong to the following classes: antiarrthymics, calcium antagonists, hypocholesterolemics, hypotensives, peripheral vessel dilators, ACE-inhibitors, beta-blockers, diuretics and sympathicomimetics. .	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: Dr.Napoleone was nominated ~~Assessor by AIFA for Rapporteur's~~ Preliminary Assessment Report for paediatric studies submitted in accordance with Article 46 of Regulation (EC) n° 191/2006,as	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)

5.1 Evidence of collaboration with regulatory authorities M	☒ Yes ☐ No Comments: Dr Ettore Napoleone is member of PWG -AIFA.PWG was formed with the aim to create continuity between the world of pediatrics and Regulatory activity both Italian and international level (EMA). PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children. PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children.FIMP (AIFA-PWG) contributed to regulatory activities with a critical revision of the benefit/risk profile of some relevant paediatric drugs (e.g. sympathomimetic nasal decongestants banned below 12aa, metocloparamide prohibited below 16aa, recommendations on tropicamide and phenylephrine , domperidone and oxatomide).A systematic analysis was conducted off-label use of medicines for children.It 'was drawn up an updated list of off-label drugs associated with the availability of scientific evidence 29 off-label drugs that are necessary to treat cardiovascular pathologies in children are legitimized by the PWG-AIFA. Thus, their use is authorized and they can be supplied by the National Health Service. Such drugs belong to the following classes: antiarrthymics, calcium antagonists, hypocholesterolemics, hypotensives, peripheral vessel dilators, ACE-inhibitors, beta-blockers, diuretics and sympathicomimetics. .	Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.
5.3 Formal meetings for clinical trials If yes, provide number	☒ Yes ☐ No Comments: 3 Investigator's meeting were organised for clinical trials	For example, investigator meetings, trainings specific to a given ongoing or planned trial.

5.1 Evidence of collaboration with regulatory authorities M	☒ Yes ☐ No Comments: Dr Ettore Napoleone is member of PWG -AIFA.PWG was formed with the aim to create continuity between the world of pediatrics and Regulatory activity both Italian and international level (EMA). PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children. PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children.FIMP (AIFA-PWG) contributed to regulatory activities with a critical revision of the benefit/risk profile of some relevant paediatric drugs (e.g. sympathomimetic nasal decongestants banned below 12aa, metocloparamide prohibited below 16aa, recommendations on tropicamide and phenylephrine , domperidone and oxatomide).A systematic analysis was conducted off-label use of medicines for children.It 'was drawn up an updated list of off-label drugs associated with the availability of scientific evidence 29 off-label drugs that are necessary to treat cardiovascular pathologies in children are legitimized by the PWG-AIFA. Thus, their use is authorized and they can be supplied by the National Health Service. Such drugs belong to the following classes: antiarrthymics, calcium antagonists, hypocholesterolemics, hypotensives, peripheral vessel dilators, ACE-inhibitors, beta-blockers, diuretics and sympathicomimetics. .	Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.
5.4 Training courses given over the last 2 years M ~~If yes, provide number~~	☒ Yes ☐ No Comments: Training courses given over the last 2 ~~years were~~ 7: a) N.6 BASIC Family Paediatricians -Investigators Course b) n.1 ADVANCED Clinical Research Master	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: Dr Ettore Napoleone is member of PWG -AIFA.PWG was formed with the aim to create continuity between the world of pediatrics and Regulatory activity both Italian and international level (EMA). PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children. PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children.FIMP (AIFA-PWG) contributed to regulatory activities with a critical revision of the benefit/risk profile of some relevant paediatric drugs (e.g. sympathomimetic nasal decongestants banned below 12aa, metocloparamide prohibited below 16aa, recommendations on tropicamide and phenylephrine , domperidone and oxatomide).A systematic analysis was conducted off-label use of medicines for children.It 'was drawn up an updated list of off-label drugs associated with the availability of scientific evidence 29 off-label drugs that are necessary to treat cardiovascular pathologies in children are legitimized by the PWG-AIFA. Thus, their use is authorized and they can be supplied by the National Health Service. Such drugs belong to the following classes: antiarrthymics, calcium antagonists, hypocholesterolemics, hypotensives, peripheral vessel dilators, ACE-inhibitors, beta-blockers, diuretics and sympathicomimetics. .	Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.
5.5 Training courses received over the last 2 years [M] ~~If yes, provide number~~	☒ Yes ☐ No Comments: Training courses received : 3 ~~(Investigator's meeting)~~	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

5.1 Evidence of collaboration with regulatory authorities M	☒ Yes ☐ No Comments: Dr Ettore Napoleone is member of PWG -AIFA.PWG was formed with the aim to create continuity between the world of pediatrics and Regulatory activity both Italian and international level (EMA). PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children. PWG was formed, with the collaboration of many experts, with a specified aim and that is to launch initiatives and measures for more rational use of the drug in children.FIMP (AIFA-PWG) contributed to regulatory activities with a critical revision of the benefit/risk profile of some relevant paediatric drugs (e.g. sympathomimetic nasal decongestants banned below 12aa, metocloparamide prohibited below 16aa, recommendations on tropicamide and phenylephrine , domperidone and oxatomide).A systematic analysis was conducted off-label use of medicines for children.It 'was drawn up an updated list of off-label drugs associated with the availability of scientific evidence 29 off-label drugs that are necessary to treat cardiovascular pathologies in children are legitimized by the PWG-AIFA. Thus, their use is authorized and they can be supplied by the National Health Service. Such drugs belong to the following classes: antiarrthymics, calcium antagonists, hypocholesterolemics, hypotensives, peripheral vessel dilators, ACE-inhibitors, beta-blockers, diuretics and sympathicomimetics. .	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:	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:	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: "One of the main characteristics of an Italian family paediatrician is a trustful and long-lasting relationship with parents, parent organizations and children which is based on 'family communication'.Families do not contribute to the creation of an institutional list of priorities, but they can certainly give excellent advice and practical suggestions on the priorities for clinical trials in children.[ANNEX n.5]	Indicate if public stakeholders are /have been involved