8 May 2012
EMA/817559/2010
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.

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

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| **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*

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|---|---|---|
| Name | National Center for Child Health and Development | Include legal address, define acronyms |
| Type | National Center (Independent Administrative Agencies) that is allied with major paediatric hospitals in Japan. | Indicate type of reporting party, e.g. national or speciality network. May include short mission statement |
| Street | 2-10-1 Okura | |
| Postal code | 157-8535 | |
| Town | Setagaya-ku, Tokyo | |
| Country | Japan | |
| Telephone 1 | +81-3-3416-0181 | |
| Telephone 2 | | |
| Mobile phone | | |
| Fax | +81-3-3417-5691 | |
| Web site | http://www.ncchd.go.jp/English/English top.htm | If available (see criterion 4) |
| Email for general enquiries | nakamura-hd@ncchd.go.jp | If available (see criterion 4) |
| Representative (main) contact | --- | Include first and second name, email, telephone, address, as far as available |
| First name | Hidefumi | |
| Second name | Nakamura | |
| Telephone | +81-3-3416-0181 | |
| Mobile phone | | |
| Email | nakamura-hd@ncchd.go.jp | |
| Further contact(s) | --- | Include first and second name, email, telephone, address, as far as available |
| First name | Nao | |
| Second name | Tsuchida | |
| Telephone | +81-3-3416-0181 | |
| Mobile phone | | |
| Email | tsuchida-n@ncchd.go.jp | |
| The data in this document are 'current' as of | 08/03/2012 | Provide the date when the criteria were last updated |
| State how this document can be accessed by the public | To be posted at the English webside in early 2011 (We currently have Japanese website only and are preparing English website) | This should be a link to a webpage, but other means and formats to make public are possible |

## *Description* [M]

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| Year of foundation | 2002 | 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 | Japanese (mainly)<br>Newborn, cardiology, neurology, neuropsychiatry, oncology,allergy, metabolism, nephrology, infection, pulmonology, genetic, rheumatology , anesthesiology, intensive care, orthopedics, surgery, dermatology, otorhinolaryngology, ophthalmology, | 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 | Multispeciality | For example, oncology or infectious diseases |
| Speciality or disease specific? Specify | Multispeciality | For example, cardiology only |
| Conditions covered? Specify | Most conditons in speciality stated above | E.g. hypertension (within cardiology) or asthma (within respiratory diseases) |
| Procedure / intervention specific? Specify | many areas of surgery and transplantation (e.g., kidney, liver and stem cell) | For example, surgery, organ or stem cell transplantation |
| Number of collaborating countries | Outside of Europe<br><br>List all collaborating countries:<br>1 (National, Japan) preparing to collaborate with China and Korea | State the number of collaborating countries.<br>Indicate "1" if national;<br>Indicate if Europe, outside of Europe, other…….<br>(describe) |

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| Number of collaborating centres | 29 (Japanese Association of Children's Hospitals and Related Institutions: JaCHRI)<br><br>List all collaborating centres:<br>Tokyo Metropolitan Children's Medical Center<br>Kanagawa Children's Medical Center<br>Osaka Medical Center and Research Institute for Maternal and Child Health<br>Hokkaido Medical Center for Child Health and Rehabilitation<br>Miyagi Children's Hospital<br>Ibaraki Children's Hospital<br>Dokkyo Medical University Tochigi Children's Medical Center<br>Jichi Children's Medical Center Tochigi<br>Gumma Children's Medical Center<br>Saitama Children's Medical Center<br>Chiba Children's Hospital<br>Kanagawa Children's Medical Center<br>Shizuoka Children's Hospital<br>Nagano Children's Hospital<br>Central Hospital, Aichi Prefectural Colony<br>Japanese Red Cross Nogoya First Hospital, Children Medical Center<br>Aichi Childen's Health and Medical Center<br>Medical Center for Children, Shiga<br>Mie National Hospital<br>Children's Research Hospital, Kyoto Prefectural University of Medicine<br>Osaka City General Hospital<br>Hyogo Prefectural Kobe Children's Hospital<br>Okayama National Hospital<br>Hiroshima Prefectural Hospital<br>Kagawa Children's Hospital<br>Fukuoka Children's Hospital and medical Center for Infectious Disease<br>St. Mary's Hospital Maternal and Child Total Health Care Center<br>Okinawa Prefectural Nanbu Medical Center, Children's Medical Center | 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 | |

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| Other activity | Consultation and Advise for Japanese Regulatory Agency and Ministries. | 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.

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| 1.1<br>Number of completed trials [M]<br>Number of ongoing trials [M] | Completed: 4<br><br>Ongoing: 22 (Apr 2009-Dec 2010) | 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<br>Total number of participants actually recruited each year<br><br>Proportion of eligible participants actually recruited each year<br><br>Describe way of screening and participant recruitment | 182:Apr 2009-Dec 2010<br><br>Neonate, Infant, Toddler, Child, Adolescent and Pregnant Female<br><br>Screened by physicians/ research nurses utilizing electronic medical record. Also utilize patient lists for some disease conditions including Growth Hormone Deficiency | Relevant to speciality specific networks.<br>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<br>Total number of collaborating centres | Completed: 27 (Apr 2009-Dec 2010), including sites other than network<br>Ongoing: A maximum of 31 (10 Dec 2010) including sites other than network) | 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<br>Number of ongoing and completed clinical trials | Absolute number:<br>Ongoing: 9 (Dec, 2010)<br>Completed: 3 (April, 2006-Dec, 2010) | Paediatric interventional trials of any phase of the pharmaceutical development (phase I to IV, |

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| | Proportion of all studies:<br>Phase 2, 2/3 and 3 | including therapy optimising trials if requiring authorisation by regulatory authority)<br>(for other Paediatric trials unrelated to drug development see below) |
| 1.5<br>Number of paediatric specialities covered by paediatric trials | Ongoing: 2 (as of 10 Dec 2010)<br>neurology, nephrology<br>Completed: 3 (Apr 2006-Dec 2010, investigator-initiated for NDA)<br>neonatology, anesthesiology, oncology | Count specialities, without repetition, across all ongoing or completed paediatric trials |
| 1.6<br>Number of paediatric conditions covered by paediatric trials | Ongoing: 3 (as of 10 Dec 2010)<br>MELAS, nephrotic syndrome, IgA nephropathy<br>Completed: 3 (Apr 2006-Dec 2010, investigator-initiated trials for NDA)<br>neonatal convulsion, anesthesia, solid tumors | If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials |
| 1.7<br>Number of other ongoing research studies / programs | Ongoing: 40 【Fiscal 2009(Apr 2009-Mar 2010) , number of continuing epidemiological studies and outcome studies reviewed by the institutional review board】 | 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<br>Indicate the proportion of public funding | Proportion of academic initiated studies:<br><br>Proportion of budget:<br>All academic paediatric trials are funded by the funding from the Ministory of Health, Labour and Welfare and/or the Ministory of Education, Culture, Sports, Science and Technology | 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<br>Number of registered study participants (all studies) | 93：Apr 2009-Dec 2010 | |
| Industry-sponsored trials | --- | |
| 1.10<br>Number of ongoing and | Ongoing: 13 (Dec 2010) | Paediatric interventional trials of any phase of the |

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| completed trials | Completed: 1 (Apr 2009-Dec 2010), | pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation) |
| 1.11<br>Number of paediatric specialities covered by paediatric trials | Ongoing: 7 (Apr 2009-Dec 2010)<br>neurology, endocrinology, infectious diseases, anesthesiology, gastroenterology, allergy, nephrology<br>Completed: 1 (Apr 2009-Dec 2010)<br>infectious diseases | Count specialities, without repetition, across all ongoing or completed paediatric trials |
| 1.12<br>Number of paediatric conditions covered by paediatric trials | Ongoing: 8 (Apr 2009-Dec 2010)<br>convulsion, vaccine, fluid replacement/ surgery, gastric ulcer, asthma, nephrotic syndrome, infection, GH deficiency<br>Completed: 1 (Apr 2009-Dec 2010),<br>vaccine | If not all areas within one speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials |
| 1.13<br>Number of registered study participants (all studies) | 89 (Apr 2009-Dec 2010) | |

## Criterion 2: Network organisation and processes

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| 2.1<br>Existence of an identified contact person for external enquiries [M] | ☒ Yes ☐ No<br><br>Comments:<br>Division chief has the sole responsibility. Thera is designated staff as a contact person for each trial | 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<br>Existence of an internal steering committee [M] | ☒ Yes ☐ No<br>Comments:<br>JaCHRI (Japanese Association of Children's Hospitals and Related Institutions) clinical trial network steering committee. Details will be officially posted at the JaCHRI website in early 2011 | Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3). |
| 2.3<br>Existence of an external advisory / steering committee directing the reporting party [M] | ☐ Yes ☒ No<br>Comments: | Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3). |
| 2.4<br>Existence of a website | ☐ Yes ☒ No<br>Comments:<br>Will be up and running by April, 2011 | If available, mention in "identification" above |
| 2.5<br>Existence of newsletter | ☐ Yes ☒ No<br>Comments:<br>First issure to be published next year | Newsletter of any format (electronic, surface mail), distributed actively to selected recipients. |
| 2.6<br>Existence of an internal database(s) for disease, condition, treatment and / or outcome [M]<br><br>If yes, please describe | ☒ Yes ☐ No<br><br>Comments / description:<br>Can be screened from the electric medical records in several hospitals<br>Additional database for certain disease conditions (e.g. growth hormone deficiency) | For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data) |
| 2.7<br>Provisions to ascertain data protection and data security [M] | ☒ Yes ☐ No<br>Comments:<br>Existence of secured data center at NCCHD. Also work with ARO for certain trials | Are provisions in place to ascertain patients' /study participants' data protection and data safety within network |

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| 2.1<br><br>Existence of an identified contact person for external enquiries [M] | ☒ Yes ☐ No<br><br>Comments:<br><br>Division chief has the sole responsibility. Thera is designated staff as a contact person for each trial | 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. |
| 2.8<br>Procedure(s) to access the database by third parties | ☐ Yes ☒ No<br>Comments: | Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)? |
| 2.9<br>Access to external databases /registries | ☐ Yes ☒ No<br>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<br>Standardised process to access an external database(s) | ☐ Yes ☒ No<br>Comments: | Is a standardised process in place to access external/ national databases? |

## Criterion 3: Scientific competencies and capacity to provide expert advice

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| 3.1<br>Number of peer-reviewed publications in the last 5 years<br>Provide exact reference(s)<br>Describe the network's contribution to publication(s) | 2 papers in English (Apr 2008-Mar 2010)<br>publications related to the network's contribution<br>Nakanishi K, Iijima K, Ishikura K, Hataya H, Awazu M, Sako M, Honda M, Yoshikawa N; Japanese Pediatric IgA Nephropathy Treatment Study Group. Efficacy and safety of lisinopril for mild childhood IgA nephropathy: a pilot study.Pediatr Nephrol, 2009, 24:845-849.<br>Nakayama M, Kamei K, Nozu K, Matsuoka K, Nakagawa A, Sako M, Iijima K. Rituximab for refractory focal segmental glomerulosclerosis. Pediatr Nephrol, 2008, 23:481-5. | The publications should indicate that they are related to and reference the reporting party. |
| 3.2<br>Number of competitive grants obtained in the last 5 years | 18 From Health, Labour and Welfare Research Grant (Apr 2008-Dec 2010) for clinical trials | Grants obtained by reporting party (exclusively or not). |
| 3.3<br>Access to expert groups M | ☒ Yes ☐ No<br>Comments:<br>Expanded committee on Drugs of the Japan Pediatric Society. This committee has representatives from all pediatric subspecialties | Indicate if the reporting party has specific access to established expert groups, such as learned societies |
| 3.4<br>Capacity to answer external scientific questions M | ☒ Yes ☐ No<br>Comments:<br>Project management team that works closely with research nurses and specialists | 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: | --- | |

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| 3.5<br>Site feasibility | ☒ Yes ☐ No<br>Comments:<br>Check list is used in addition to specific trial recruitment | This concerns the suitability of a site for conducting a given trial |
| 3.6<br>Participant recruitment | ☒ Yes ☐ No<br>Comments:<br>For 9 multicenter-trials (4 investigator-initiated trials for NDA and 5 paediatric interventional trials), projectmanagement team at NCCHD regularly monitor participant recruitment | This concerns provisions to regularly monitor recruitment progress for a trial. |
| 3.7<br>Budget calculation for studies | ☒ Yes ☐ No<br>Comments:<br>Projectmanagement team at NCCHD support principal investigators for financial planning. | This concerns, for example, quotes and prospective financial planning for a trial. |

## Criterion 4: Quality management

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| 4.1<br><br>Documented adherence to Good Clinical Practice (GCP) guideline [M] | ☒ Yes ☐ No<br><br>Comments:<br><br>Japanese GCP and ICH-GCP. This also means adherence to EU Directive 2001/20/EC is assured. | Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials. |
| 4.2<br>Documented adherence to the ethical considerations for clinical trials in children [M] | ☒ Yes ☐ No<br>Comments:<br>Adherence to the local guidance , Japanese Ethical Considerations for Clinical Researches (Rinsyo-kenkyu ni kansuru rinri-shishin), is documented. Investigation on the adherence to the EU "Ethical considerations for clinical trials in chidlren" is currently underway. | 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<br>Documented adherence to ethical considerations | ☒ Yes ☐ No<br>Comments:<br>Adhere to the Japanese ethical Considerations for Clinical Researches (Rinsyo-kenkyu ni kansuru rinri-shishin, etc) is checked by the institutinal review board before initiation of studies | Declare whether reporting party requests approval by an independent ethics committee with paediatric expertise for all studies conducted. |
| 4.4<br>Availability of Standard Operation Procedures (SOP) | ☒ Yes ☐ No<br>If yes, provide reference to available SOPs<br>For funded research, SOP for the following is available: investigator-initiated clinical trials for NDA, adverse events reporting, monitaring, audit and institutional review board, project management<br><br>Posted at:<br>http://www.ncchd.go.jp/center/clinical/chiken-sop.html (in Japanese) | Indicate existence of SOP e.g. for study management, adverse events reporting etc. |
| 4.5<br>Capacity to monitor studies (academic trials, industry sponsored trials) [M] | ☒ Yes ☐ No<br>Comments:<br>Central monitoring for 5 academic trials<br>Both central and local monotoring for 4 investigator-initiated trials for NDA | Indicate if the reporting party implements the monitoring of paediatric trials according to ICH 6 Good Clinical Practice Guideline. |

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| 4.6<br>Capacity to monitor performance of collaborating centres | ☒ Yes ☐ No<br>Comments:<br>Performance monitoring for 10 clinical trials (Apr 2009 -Dec 2010) | Indicate if the reporting party implements the monitoring of performance of collaborating centres. |
| 4.7<br>Quality control and quality assurance, traceability and data safety [M] | ☒ Yes ☐ No<br>Comments:<br>For 5 academic trials<br>and 4 investigator-initiated trials for NDA | Indicate if this is implemented in the reporting party's remit. |

## Criterion 5: Training and educational capacity to build competences

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| 5.1<br><br>Evidence of collaboration with regulatory authorities [M] | ☒ Yes ☐ No<br><br>Comments:<br><br>4 members at pediatric working group of the Study group on unlicensed and off-label drugs (Ministory of Health, Labour and Welfare)<br><br>3 advisors for the Japaense regulatory agency (PMDA)<br><br>3 former reviewers and 1 former auditor who have had experiences at the regulatory agency<br><br>2 staff experienced in drug development in a industry | Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities. |
| 5.2<br>Capacity to provide competent consultation to regulatory authorities | ☒ Yes ☐ No<br>Comments:<br>3 members at the advisory board for the PMDA<br>3 former reviewers and 1 former auditor who have had experiences at the regulatory agency | 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<br>Formal meetings for clinical trials<br>If yes, provide number | ☒ Yes ☐ No<br>Comments:<br>1-2 meetings per year per trial | For example, investigator meetings, trainings specific to a given ongoing or planned trial. |
| 5.4<br>Training courses given over the last 2 years [M]<br>If yes, provide number | ☒ Yes ☐ No<br>Comments:<br>6 times (Apr 2009 -Dec 2010) | 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). |

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| 5.5<br>Training courses received over the last 2 years [M]<br>If yes, provide number | ☒ Yes ☐ No<br>Comments:<br>Approximately 60 courses (e.g. Each course was attended by at leaset one investigator) | For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party.<br>Minimum requirement (M): training courses either given (5.4) or received (5.5). |
| 5.6<br>Promotion of participation in clinical trials in countries with limited resources<br><br>Provide list of countries | ☐ Yes ☒ No<br>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.

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| 6.1<br>Involvement of patients, parents or their organisations in the protocol design | ☒ Yes ☐ No<br>Comments:<br>In some of the trials including allergy. Will officially have representatives of a patient organaization involved starting 2011 | Indicate if public stakeholders are /have been involved |
| 6.2<br>Involvement of patients, parents or their organisations in creating the protocol information package | ☐ Yes ☒ No<br>Comments: | Indicate if public stakeholders are /have been involved |
| 6.3<br>Involvement of patients, parents or their organisations in the prioritisation of needs for clinical trials in children | ☐ Yes ☒ No<br>Comments: | Indicate if public stakeholders are /have been involved |