EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2010
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Human Medicines Development and Evaluation

European network of paediatric research (EnprEMA)

Recognition criteria for self assessment

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

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

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

END OF SELF-ASSESSMENT PERIOD	31 July 2010

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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	UKPVG. United Kingdom Paediatric Vaccines Group	Include legal address, define acronyms
Type	Speciality network: paediatric vaccines. The UK Paediatric Vaccine Group (UKPVG) is an independent network of research institutions, which through collaboration, aims to further education, training and high quality research in the field of paediatric vaccines.	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	Vaccine Institute, St Georges, University of London, Cranmer Terrace	
Postal code	SW170RE	
Town	London	
Country	UK	
Telephone 1	020 87255980	
Telephone 2		
Mobile phone		
Fax	020 87253262	
Web site	www.ukpvg.org	If available (see criterion 4)
Email for general enquiries	secretariat@ukpvg.org	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Paul	
Second name	Heath	
Telephone	020 87255980	
Mobile phone	07956144122	
Email	pheath@sgul.ac.uk	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Matthew	
Second name	Snape	
Telephone	01865 857420	
Mobile phone	07837 587 361	
Email	Matthew.Snape@paediatrics.ox.ac.uk	

The data in this document are 'current' as of	25/7/10	Provide the date when the criteria were last updated
State how this document can be accessed by the public	http://www.ukpvg.org/ukpvg/internet/en/tools/contact.html	This should be a link to a webpage, but other means and formats to make public are possible

Description [M]

Year of foundation	2001	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	Vaccinology	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 diseases, immunology, epidemiology, public health	For example, oncology or infectious diseases
Speciality or disease specific? Specify	Vaccinology	For example, cardiology only
Conditions covered? Specify	-	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify	Immunisation	For example, surgery, organ or stem cell transplantation

Number of collaborating countries	1 List all collaborating countries: England	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe)
Number of collaborating centres	5 List all collaborating centres: -Oxford Vaccine Group, University of Oxford, Oxford -Bristol Children's Vaccine Centre, Bristol -University of Southampton Wellcome Trust Clinical Research Facility, Southampton -Health Protection Agency & National Vaccine Evaluation Consortium -St Georges Vaccine Institute, London.	State the number of collaborating centres and provide a list of all collaborating centres (attachment or link possible)
Type of activity/studies		
Clinical studies	☒ Yes ☐ No	
Experimental research	☒ Yes ☐ No	
Other activity	Public education promoting vaccines and research, participant and public involvement in research.	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]	5 6	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	Over 2700 participants in total varies from 2% for healthy child studies to 60% for follow up studies Healthy infant / child studies: subjects identified from regional routine immunisation lists or GP practice lists and approached by letter or through use of hospital / university staff email lists and study website. Specific disease vaccination studies: subjects identified from databases and approached by letter.	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	5	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: 1 Proportion of all studies: 0.1	Paediatric interventional trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising

		trials if requiring authorisation by regulatory authority) (for other Paediatric trials unrelated to drug development see below)
1.5 Number of paediatric specialities covered by paediatric trials	1	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 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 paediatric trials
1.7 Number of other ongoing research studies / programs	0	For example, epidemiological studies, outcome studies, translational research in which the reporting party is participating Include cohort studies but not audits. Research is defined as a project with a specific research question in which the participant/family provides formal consent.
1.8 Indicate the proportion of public funding	Proportion of academic initiated studies: 0.1 Proportion of budget: 0.1	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)	945	
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	10	Paediatric interventional trials of any phase of the pharmaceutical development (phase I to IV, including therapy optimising trials if requiring authorisation)

1.11 Number of paediatric specialities covered by paediatric trials	1	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 paediatric trials
1.13 Number of registered study participants (all studies)	1760	

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: all centres have own contact details on respective websites. Central contact for UKPVG is secretariat@ukpvg.org	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: 1 Lead (and nominated deputy) from each of the 5 collaborating centres	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: External steering committees have been established for specific studies where required, and the UKPVG have initiated the process of appointing a standing external steering committee.	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:	If available, mention in "identification" above
2.5 Existence of newsletter	☐ Yes ☒ No Comments: Email list of all members maintained by secretariat and used to distribute relevant information, agendas for meetings etc. A brochure outlining the membership and activity of the UKPVG has also been prepared.	Newsletter of any format (electronic, surface mail), distributed actively to selected recipients.
2.6 Existence of an internal database(s) for disease, condition, treatment and / or outcome [M] If yes, please describe	☐ Yes ☒ No Comments / description: A number of databases for different patient groups can be accessed for potential studies. Examples include regional routine child health immunisation registers, email list for hospital staff employees, condition-specific databases held at individual hospitals	For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data)

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: all centres have own contact details on respective websites. Central contact for UKPVG is secretariat@ukpvg.org	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.
2.7 Provisions to ascertain data protection and data security [M]	☒ Yes ☐ No Comments: All studies conducted according to relevant data protection guidelines, with participant personal identifying data held on secure electronic networks or locked cupboards.	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: Anonymised data are shared within the network as required under appropriate data protection guidelines	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: With ethical permission (which is study specific), access is possible to a range of relevant databases	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: Certain external databases (eg. regional routine child health immunisation registers) are commonly accessed using a standardised approach	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)	5 Safety and immunogenicity of AS03B adjuvanted split virion versus non-adjuvanted whole virion H1N1 influenza vaccine in UK children aged 6 months-12 years: open label, randomised, parallel group, multicentre study. Waddington CS, Walker WT, Oeser C et al BMJ. 2010 ;340: c2649 Future of Flu Vaccines: Expediting Clinical Trials in a Pandemic. Pollard AJ, Reiner A, John T, Sheasby E, Snape M, Faust S, Collinson A, Finn A, Heath PT, Miller E. BMJ. 2009 ;339:4652 Immunogenicity and reactogenicity of a 13-valent pneumococcal conjugate vaccine administered at 2, 4 and 12 months of age: a double-blind randomized active-controlled trial. Matthew D Snape, Chaam L Klinger, Elvis D Daniels at al. Pediatr Inf Dis J. (In press). Immunogenicity and induction of immunological memory of the heptavalent pneumococcal conjugate vaccine in preterm UK infants. Ruggeberg JU, Collins C, Clarke P, et al. Vaccine. 2007 Jan 4;25(2):264-71 Immunogenicity and immunologic memory of meningococcal C conjugate vaccine in premature infants. Collins CL, Ruggeberg JU, Balfour G, et al. Pediatr Infect Dis J. 2005 Nov;24(11):966-8. Collaborative studies undertaken by at least 2 of the UKPVG centres	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	1	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups [M]	☒ Yes ☐ No Comments: European Society of Paediatric Infectious Diseases, Medicines for Children Research Network, Royal College of Paediatric and Child Health, European Medicines Agency, British Paediatric Allergy, Infection and Immunity Group.	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: Coordinated by secretariat with email communication to UKPVG internal steering group members	Indicate if coordinated capacity (staff, process) is available to answer external scientific questions in relation to clinical trials during daily business.
Standardized procedures for assessment of:	---	
3.5 Site feasibility	☒ Yes ☐ No Comments: UKPVG members assess suitability of sites available to them. Suitability will depend on study / trial	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments: Several studies currently sponsored by University of Oxford with standardised procedures for clinical trials in place, including coordination of weekly review of recruitment by Oxford site.	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: Budgets for commercial studies usually based on NIHR commercial costing template http://www.ukcrn.org.uk/index/industry/costing.html.	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: Prerequisite for any clinical trial and monitored by Sponsor relevant to each study	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: Prerequisite for any clinical trial involving children and monitored by Sponsor relevant to each study. In the UK all ethics committees are required under the Clinical Trials Regulations to have advice from a member with professional expertise in paediatric care for studies involving children (see http://www.nres.npsa.nhs.uk/news-and-publications/publications/standard-operating-procedures/).	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: Prerequisite for all studies	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 All sites have own SOPs, often standardised across all sites. No external links available.	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: Monitored by relevant Sponsor for each study. For non-industry sponsored studies monitoring is performed by representatives of the lead site, and is facilitated by use of electronic clinical trial databases.	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: Monitored by lead centre for each study, with regular (up to weekly) teleconferences between UKPVG members to review performance and discuss any concerns.	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: Monitored by relevant Sponsor for each study, with a designated quality assurance lead for each non-industry sponsored study.	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: UKPVG centres have been inspected by Vaccine Manufacturers, by MHRA and by the Health and Safety Executive on various occassions.	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: Have capacity to provide expert advice	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: As required for studies. Approximately 15 'face to face' meetings over the last 5 years, along with frequent teleconferences to dscuss study planning and progress.	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: Training is provided by Lead Centre and / or Sponsor for other centres for individual studies that take place in the network	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: As above	For example, training specific to a trial or in general for trial(s), with external participants or from the reporting party. Minimum requirement (M): training courses either given (5.4) or received (5.5).

5.6 Promotion of participation in clinical trials in countries with limited resources Provide list of countries	☒ Yes ☐ No Comments: Individual centres within the network provide support for such trials. Nepal, Togo, Fiji.	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: Individual centres within the network have involved parents or parent groups in studies, especially in design of information sheets	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