22 February 2012
EMA/817619/2010
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	German Neonatal Network (GNN)	Include legal address, define acronyms
Type	National Network foccussed on clinical and genetic influences on the long term development of preterm infants.	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	Klinik für Kinder- und Jugendmedizin, Ratzeburger Allee 160	
Postal code	23538	
Town	Lübeck	
Country	Germany	
Telephone 1	+49 451 500 2644	
Telephone 2	+49 451 500 2555	
Mobile phone		
Fax	+49 451 500 6986	
Web site	www.vlbw.de	If available (see criterion 4)
Email for general enquiries	lorenz@vlbw.de	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Prof. Wolfgang	
Second name	Göpel	
Telephone	+49 451 500 2555	
Mobile phone		
Email	goepel@vlbw.de	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Christoph	
Second name	Härtel	
Telephone	+49 451 500 2685	
Mobile phone		
Email	haertel@paedia.ukl.mu-luebeck.de	
The data in this document are 'current' as of	19.12.2011	Provide the date when the criteria were last updated

Name	German Neonatal Network (GNN)	Include legal address, define acronyms
State how this document can be accessed by the public	www.vlbw.de	This should be a link to a webpage, but other means and formats to make public are possible

Description M

Year of foundation	2008	Of the network, or of the investigator's or site's specific paediatric research activities
Paediatric age ranges of study participants covered by the network		
Preterm and / or term newborn	☒ Yes ☐ No	Newborn: from birth to less than 28 days of age
Infants from 1 month to less 24 months of age	☒ Yes ☐ No	
Children from 2 years to less than 12 years of age	☒ Yes ☐ No	
Adolescents from 12 years to less than 18 years	☐ Yes ☒ No	
Specialities / Conditions covered	Diseases and long-term development of preterm infants.	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, pulmonary diseases, gastrointestinal diseases and growth retardation, neurologic complications and developmental delay.	For example, oncology or infectious diseases
Speciality or disease specific? Specify		For example, cardiology only
Conditions covered? Specify	Respiratory distress syndrome, sepsis, necrotizuing enterocolitis, bronchopulmonary dysplasia, intraventricular haemorrhage, retinopathy of prematurity, fetal growth restriction and postnatal growth retardation.	E.g. hypertension (within cardiology) or asthma (within respiratory diseases)
Procedure / intervention specific? Specify		For example, surgery, organ or stem cell transplantation

Year of foundation	2008	Of the network, or of the investigator's or site's specific paediatric research activities
Number of collaborating countries	1 List all collaborating countries: Germany	State the number of collaborating countries. Indicate "1" if national; Indicate if Europe, outside of Europe, other……. (describe)
Number of collaborating centres	38 List all collaborating centres: www.vlbw.de	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		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	Completed: 1 The AMV-trial. A randomized controlled interventional trial comparing a new method of surfactant application in vlbw-infants with standard treatment. Endpoint: Mechanical ventilation. (Trial registration: ISRCTN 05025922). Ongoing: 1 The NINSAPP trial. A randomized controlled interventional trial in vlbw-infants. (Trial registration: ISRCTN 64011614). Furthermore several neonatal intensive care units (NICUs) which are members of the GNN include preterm patients into additional randomized trials like the PHELBI-trial (ISRCTN 56143743) and the NEUROSIS trial (ISRCTN 80181452).	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	1500 70% Preterm infants with a birth weight below 1500 grams are screend and recruited in all participating centers.	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	46	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	Absolute number:	Paediatric interventional

1.1 Number of completed trials [M] Number of ongoing trials [M]	Completed: 1 The AMV-trial. A randomized controlled interventional trial comparing a new method of surfactant application in vlbw-infants with standard treatment. Endpoint: Mechanical ventilation. (Trial registration: ISRCTN 05025922). Ongoing: 1 The NINSAPP trial. A randomized controlled interventional trial in vlbw-infants. (Trial registration: ISRCTN 64011614). Furthermore several neonatal intensive care units (NICUs) which are members of the GNN include preterm patients into additional randomized trials like the PHELBI-trial (ISRCTN 56143743) and the NEUROSIS trial (ISRCTN 80181452).	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.
Number of ongoing and completed clinical trials	2 Proportion of all studies: 100	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	2	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	4	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

1.1 Number of completed trials [M] Number of ongoing trials [M]	Completed: 1 The AMV-trial. A randomized controlled interventional trial comparing a new method of surfactant application in vlbw-infants with standard treatment. Endpoint: Mechanical ventilation. (Trial registration: ISRCTN 05025922). Ongoing: 1 The NINSAPP trial. A randomized controlled interventional trial in vlbw-infants. (Trial registration: ISRCTN 64011614). Furthermore several neonatal intensive care units (NICUs) which are members of the GNN include preterm patients into additional randomized trials like the PHELBI-trial (ISRCTN 56143743) and the NEUROSIS trial (ISRCTN 80181452).	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.
		research question in which the participant/family provides formal consent.
1.8 Indicate the proportion of public funding	Proportion of academic initiated studies: 100% Proportion of budget: 90%	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)	2500	
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	0	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12	0	If not all areas within one

1.1 Number of completed trials [M] Number of ongoing trials [M]	Completed: 1 The AMV-trial. A randomized controlled interventional trial comparing a new method of surfactant application in vlbw-infants with standard treatment. Endpoint: Mechanical ventilation. (Trial registration: ISRCTN 05025922). Ongoing: 1 The NINSAPP trial. A randomized controlled interventional trial in vlbw-infants. (Trial registration: ISRCTN 64011614). Furthermore several neonatal intensive care units (NICUs) which are members of the GNN include preterm patients into additional randomized trials like the PHELBI-trial (ISRCTN 56143743) and the NEUROSIS trial (ISRCTN 80181452).	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.
Number of paediatric conditions covered by paediatric trials		speciality covered count conditions, without repetition, across all ongoing or completed paediatric trials
1.13 Number of registered study participants (all studies)	0	

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments:	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: Members of the internal steering committee are Prof. Herting and Prof. Göpel (University of Lübeck, Department of Paediatrics) and Prof. Ziegler (University of Lübeck, Institute of Medical Biometry and Statistics).	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: Members of the external advisory committee are: Prof. Heike Rabe, Brighton and Sussex University Hospitals NHS Trust, UK; Prof. Jens Möller, Kinderklinik Saarbrücken on behalf of the European Society of Neonatology and Paediatric Intensive Care (ESPNIC), Prof. Wolke, University of Warwick, UK; Dr. Kurth, Robert-Koch Institut, Berlin; Prof. Thyen, University of Lübeck, Department of Paediatrics, Prof. Gembruch, University of Bonn, Department of Obstetrics; Silke Mader on behalf of the parents organisation "European foundation for the care of newborn infants" (EFCNI), Hans-Jürgen Wirthl on behalf of the parents organisation "Bundesverband Das frühgeborene Kind ev".	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

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments:	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.
2.5 Existence of newsletter	☒ Yes ☐ No Comments:	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: The GNN-database includes individual tratment and outcome data of more than 5000 preterm infants with a birth weight below 1500 grams. This databases is an important tool for the planning of furture trials.	For example, data base or disease registry to facilitate planning or conducting future trials (may or may not contain individual patient data)
2.7 Provisions to ascertain data protection and data security [M]	☒ Yes ☐ No Comments: All clinical and personal data of participants in our network are "pseudonymised" ie. personal data like names and dates are deleted and all samples and data are identified with numbers. After completion of follow-up, all data will be anonymised.	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: Participants of the GNN-network use the database as a resource for planning and conducting trials	Are provisions in place that data can be shared for planning, conducting or analysing a trial(s)?
2.9 Access to external databases /registries	☒ Yes ☐ No Comments:	For example, national databases that are not publicly accessible but to which the reporting party has open or privileged access; database(s) immediately relevant to area and / or scope
2.10 Standardised process to access an external database(s)	☐ Yes ☒ No Comments:	Is a standardised process in place to access external/ national databases?

Criterion 3: Scientific competencies and capacity to provide expert advice

3.1 Number of peer-reviewed publications in the last 5 years Provide exact reference(s) Describe the network's contribution to publication(s)	14 Göpel W et al . Genes Immun 2006, 7:65-8. Härtel C et al. Pediatrics 2006, 118:683-9. Göpel W Pediatrics 2006, 117:2285-6. Härtel C et al. Neonatology 2007; 91:54-60. Härtel C et al. Acta Paediatr 2007 96:158-65. Härtel C et al. Arch Dis Child Fetal Neonatal Ed. 2008, 93:F140-5. Spiegler J et al. J Pediatr Gastr Nutr 2008, 46:113-6. Härtel C et al . Hum Immunol 2008, 69:338-43. Spiegler J et al. Neonatology 2010; 97:10-4. Härtel C et al. J Pediatr Gastr Nutr 2009, 48:464-70. Kribs A et al. Klin Padiatr 2010;222:13-7. Krueger M et al. Arch dis Cild Fetal neonatal Ed. 2011; 96:F299-300. Härtel C et al. Crit Care Med 2011; 39:1190-5. Göpel W et al: Lancet 2011; 378:1627-34. The GNN provides data or results of genetic studies. Since the network was founded in November 2008, the above publications do not contain the term "GNN", which is already integrated in several manuscripts which are now in review.	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	5	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups M	☒ Yes ☐ No Comments:	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)	14 Göpel W et al . Genes Immun 2006, 7:65-8. Härtel C et al. Pediatrics 2006, 118:683-9. Göpel W Pediatrics 2006, 117:2285-6. Härtel C et al. Neonatology 2007; 91:54-60. Härtel C et al. Acta Paediatr 2007 96:158-65. Härtel C et al. Arch Dis Child Fetal Neonatal Ed. 2008, 93:F140-5. Spiegler J et al. J Pediatr Gastr Nutr 2008, 46:113-6. Härtel C et al . Hum Immunol 2008, 69:338-43. Spiegler J et al. Neonatology 2010; 97:10-4. Härtel C et al. J Pediatr Gastr Nutr 2009, 48:464-70. Kribs A et al. Klin Padiatr 2010;222:13-7. Krueger M et al. Arch dis Cild Fetal neonatal Ed. 2011; 96:F299-300. Härtel C et al. Crit Care Med 2011; 39:1190-5. Göpel W et al: Lancet 2011; 378:1627-34. The GNN provides data or results of genetic studies. Since the network was founded in November 2008, the above publications do not contain the term "GNN", which is already integrated in several manuscripts which are now in review.	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:	---	
3.5 Site feasibility	☒ Yes ☐ No Comments:	This concerns the suitability of a site for conducting a given 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)	14 Göpel W et al . Genes Immun 2006, 7:65-8. Härtel C et al. Pediatrics 2006, 118:683-9. Göpel W Pediatrics 2006, 117:2285-6. Härtel C et al. Neonatology 2007; 91:54-60. Härtel C et al. Acta Paediatr 2007 96:158-65. Härtel C et al. Arch Dis Child Fetal Neonatal Ed. 2008, 93:F140-5. Spiegler J et al. J Pediatr Gastr Nutr 2008, 46:113-6. Härtel C et al . Hum Immunol 2008, 69:338-43. Spiegler J et al. Neonatology 2010; 97:10-4. Härtel C et al. J Pediatr Gastr Nutr 2009, 48:464-70. Kribs A et al. Klin Padiatr 2010;222:13-7. Krueger M et al. Arch dis Cild Fetal neonatal Ed. 2011; 96:F299-300. Härtel C et al. Crit Care Med 2011; 39:1190-5. Göpel W et al: Lancet 2011; 378:1627-34. The GNN provides data or results of genetic studies. Since the network was founded in November 2008, the above publications do not contain the term "GNN", which is already integrated in several manuscripts which are now in review.	The publications should indicate that they are related to and reference the reporting party.
3.6 Participant recruitment	☒ Yes ☐ No Comments:	This concerns provisions to regularly monitor recruitment progress for a trial.
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: All clinical studies (see 1.1.) within the network are in adherence to GCP. Furthermore procedures in the GNN-network itself are committed to GCP-guidelines and the GNN-network was approved by all ethical boards of all participating hospitals.	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: As mentioned above (4.1.) all parts of the GNN-network and in addition all clinical trials integrated in the network are approved by ethic committees whose decisions are committed to "Ethical considerations for clinical trials on medicinal products conducted with the paediatric population" and other guidelines.	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: See 4.1 and 4.2. Most of the ethics committees involved in the approval of our trials have 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	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: Our study-team is able to monitor clinical trials involving infants participating in the GNN-Network, since monitoring procedurs (on-site monitoring visits each 6 months) are part of our study protocol.	Indicate if the reporting party implements the monitoring of paediatric trials according to ICH 6 Good Clinical Practice Guideline.
4.6 Capacity to monitor performance of collaborating centres	☒ Yes ☐ No Comments:	Indicate if the reporting party implements the monitoring of performance of collaborating centres.

4.1 Documented adherence to Good Clinical Practice (GCP) guideline M	☒ Yes ☐ No Comments: All clinical studies (see 1.1.) within the network are in adherence to GCP. Furthermore procedures in the GNN-network itself are committed to GCP-guidelines and the GNN-network was approved by all ethical boards of all participating hospitals.	Declare whether studies conducted comply with the EU Directive 2001/20/EC on Clinical Trials.
4.7 Quality control and quality assurance, traceability and data safety M	☒ Yes ☐ No Comments: As mentioned above, regular on-site monitoring is implemented in our study protocol to ensure high data quality. Furthermore, cross-checks are implemented in our database (e.g. are documented days of mechanical ventilation reliable or is the number of days with ventilation higher than expected in an infant with the given gestational age and birth weight). To ensure traceability and data safty we use a data tracking system and data are stored on two secured servers in different parts of our hospital. Furthermore regular back-ups are done on CD.	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: For clinical trials conducted in the GNN an increasing number of physicians has been trained in special courses (in Germany they are called "Prüfarztkurse"), where according guidelines and regulations are explained.	Indicate awareness of regulatory requirements for developing medicines; for example, implementation of guidelines from regulatory authorities.
5.2 Capacity to provide competent consultation to regulatory authorities	☒ Yes ☐ No Comments:	Indicate the capacity of the reporting party to provide expert advice to regulatory authorities. For example, nominations into standing scientific committees to regulatory authorities, registration(s) as authorities' external expert(s).
5.3 Formal meetings for clinical trials If yes, provide number	☒ Yes ☐ No Comments:	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: The Institute of Medical Biometry and Statistics at the University of Lübeck, which is involved in the GNN, provided 3 training courses in 2010. Furthermore, other institutions like "Zentrum für Klinische Studien Köln", which was involved in the AMV-trial, provided several training courses in 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).
5.5 Training courses received over the last 2 years [M] If yes, provide number	☒ Yes ☐ No Comments: Approximately 10 physicians participating in the GNN received training courses in 2011.	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: For clinical trials conducted in the GNN an increasing number of physicians has been trained in special courses (in Germany they are called "Prüfarztkurse"), where according guidelines and regulations are explained.	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: Patient organisations were involved in the design of the GNN-study. They are also members of the external advisory committee.	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: Patient organisations were involved in the design of the GNN-study. Since the GNN is not developing or marketing medications, we are not able to involve parents organisations in creating package informations.	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: The need for specific clinical trials is discussed in advisory committee meetings and parents organisations are involved in the priorisation of specific trial proposals.	Indicate if public stakeholders are /have been involved