8 April 2013
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Human Medicines Development and Evaluation

European network of paediatric research (Enpr-EMA)

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: Enprema@ema.europa.eu

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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	HOSPITAL SANT JOAN DE DÉU (St.JOHN OF GOD HOSPITAL)	Include legal address, define acronyms
Type	Children's and Maternity Center (specialised pediatric center, reference at National level) Organisation completely open to the community, accessible and close by, with the ability to teach and do research; and where the focus is on the values we are known for: hospitality and solidarity	Indicate type of reporting party, e.g. national or speciality network. May include short mission statement
Street	Pg. Sant Joan de Déu, 2	
Postal code	08950	
Town	Esplugues de Llobregat	
Country	SPAIN	
Telephone 1	+34 93 253 21 00	
Telephone 2	+34 93 600 97 33	
Mobile phone	+34 610 58 14 29	
Fax	+34 93 203 39 59	
Web site	http://www.hsjdbcn.org/	If available (see criterion 4)
Email for general enquiries	info@hsjdbcn.org	If available (see criterion 4)
Representative (main) contact	---	Include first and second name, email, telephone, address, as far as available
First name	Jaime	
Second name	Pérez Payarols	
Telephone	+34 93 600 97 67	
Mobile phone	+34 93 600 97 67	
Email	Jperezpayarols@hsjdbcn.org Director of Innovation and Research Hospital Sant Joan de Déu	
Further contact(s)	---	Include first and second name, email, telephone, address, as far as available
First name	Joana	
Second name	Claverol Torres	

Name	HOSPITAL SANT JOAN DE DÉU (St.JOHN OF GOD HOSPITAL)	Include legal address, define acronyms
Telephone	+34 93 600 97 33	
Mobile phone	+34 610 58 14 29	
Email	claverol@fsjd.org Clinical research Unit Maternity block, 5th floor Pg. Sant Joan de Déu, 2 Esplugues de Llobregat, Barcelona 08950 Spain	
The data in this document are 'current' as of	February 28th, 2013	Provide the date when the criteria were last updated
State how this document can be accessed by the public	http://www.fsjd.org/es/unid-ensayos-cl%C3%ADnicos_40359	This should be a link to a webpage, but other means and formats to make public are possible

Description M

Year of foundation	Sant Joan de Deu Foundation, the Foundation leading the Reserach in Sant joan de Deu Hospital, was created in 2003	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	Allergy and Clinical Immunology Pneumology Histopathology Anesthesiology Cardiology / Heart Disease Cardiac and Vascular Surgery Arrhythmias and pacemakers Unit Surgery (Laparoscopic, Craniomaxillofacial, Neonatal, Oncological, General Pediatric and Digestive, Urological) Pediatric intensive care / critical area	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

	Palliative care Dermatology Laboratory diagnosis Biochemistry Cytogenetics Molecular Genetics Hematology Microbiology Endocrinology Gastroenterology, hepatology and nutrition Clinical Genetics Gynecology and Obstetrics Clinical Hematology Nephrology Neonatology Neurosurgery Neurology Neurophysiology Infectious Diseases Sudden Infant Death Pediatric Rheumatology Unit specialized in Developmental Disorders / Autism Emergency Early childhood development Center Inborn errors of metabolism Comprehensive Treatment Unit Neuromuscular disease treatment Unit Unit learning disability schools Dentistry and Orthodontics Ophthalmology Oncology Orthopedics , Traumatology and Rehabilitation Functional regeneration of the child amputee Otolaryngology General Pediatrics Sexual abuse and child abuse Psycology and Psychiatry	
Multispeciality? Specify	All pediatric specialities and obstetry and gynecology	For example, oncology or infectious diseases
Speciality or disease specific? Specify	N/A	For example, cardiology only
Conditions covered? Specify	• Heart Area Cardiology	E.g. hypertension (within cardiology) or asthma

	Arrhythmias Cardiosurgery Hemodynamic • Women Department Gynecology Pelvic floor Reproductive Medicine (sterility, Infertility and contraception) Obstetrics Pregnancy and maternal-fetal risk Prenatal diagnostics • Surgery Digestive Maxillofacial Neonatal Oncology Plastic Thoracic Urological • Dermatology Hemangiomas • Image Diagnosis • Endocrinology Diabetes Obesity Disorders of metabolism • Pharmacy • Gastroenterology Inflammatory Diseases Celiac Disease • Nephrology Kidney Transplant Peritoneal Dialysis • Neurosurgery Craniosynostosis Surgery for epilepsy • Neurology Inborn errors of metabolism Neuromuscular disease Epilepsy Sleep Disorders Early stimulation Developmental disorders (autism) Learning Disorders Unit School for support in learning disorders • Ophthalmology retinoblastoma strabismus Corneal transplant	(within respiratory diseases)

	neonatal retinopathy • Oncology Genetic predisposition to cancer Tumor development • Orthopedics and Traumatology scoliosis brachial plexus foot boat Malformations and extensions bone tumors amputees • Otorhinolaryngology hearing loss Laser means high • Pediatrics Abuse of minors Cystic fibrosis / pulmonology infectious Diseases Rheumatology international health • Physical Medicine and Rehabilitation Hereditary ataxias and paraplegia • Mental health addictions Developmental disorders (autism) Eating Disorders (anorexia nervosa, bulimia) Specialized Treatment Unit Deficit Disorder Attention Unit Hyperactivity Disorder (ADHD) Behavioral disorders Unit first psychotic episodes Functional Unit of child Maternal Mental Health Unit Unit for Affective Disorders and suicide • Transplantation Umbilical-cord blood donation Cornea Bone-marrow Kidney Frozen ovary	
Procedure / intervention specific? Specify	• Surgery Cardiac and Vascular Surgery Laparoscopic Craniomaxillofacial Neonatal Oncological General Pediatric and digestive	For example, surgery, organ or stem cell transplantation

	Urological Neurosurgery (craniosynostosis, Surgery for epilepsy) Amputees • Transplantation Umbilical-cord blood donation Cornea Bone-marrow Kidney Frozen ovary	
Number of collaborating countries	National, Europe, Southamerica and Northamerica List all collaborating countries: UK, Germany, Italy, France, Argentina and USA	State the number of collaborating countries. Indicate “1” if national; Indicate if Europe, outside of Europe, other……. (describe)
Number of collaborating centres	9 List all collaborating centres: Parc Sanitari Sant Joan de Déu -Spain www.pssjd.org Hospital Clínic Barcelona-Spain www.hospitalclinic.org Düsseldorf University Hospital - Germany www.uniklinik-duesseldorf.de/en/home/ Great Ormond Street Hospital-UK http://www.gosh.nhs.uk/ Hôpital Necker- Enfants Malades Paris-France http://hopital-necker.aphp.fr/ Ospedale Pediatrico Meyer-Italy http://www.meyer.it/ Ospedale Bambino Jesu-Italy http://www.ospedalebambinogesu.it/Portale2008/Default.aspx?IdOwner=1 Hospital de Pediatría S.A.M.I.C. "Prof. Dr. Juan P. Garrahan, Buenos Aires-Argentina http://www.garrahan.gov.ar/ St.Jude Childre'ns Research Hospital-USA http://www.stjude.org/stjude/v/index.jsp?vgnextoid=f87d4c2a71fca210VgnVCM1000001e0215acRCRD	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	Trainings and education (Pharos: Health disease education portal) Hospital Twinning with St. John of God Republic of Sierra Leone Innovations and patents (10 patents, 2 spin-off)	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]	53 completed trials between 2008 and 2012 50 ongoing trials (for further details, see website http://www.fsjd.org/en/hsjd-trials_40621)	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	Randomized patients per year: 2008: 54 2009: 58 2010: 105 2011: 129 2012: 241 90% of eligible participants are randomized There is a SOP which describes the recruitment process. Patients included in the studies are recruited from researcher's own inquiry. In most trials, we treat rare diseases, and these cases are already identified. All unit physicians are informed about the clinical trial so they can identify potential candidates. If the study might include patients from various specialties, we establish a multidisciplinary team that involves investigators from the different services.The hospital is a reference hospital at national level for many rare diseases. in this regard, we usually won't have any problem. An addition point to mention is that we perform a very rigourous feasibility before accepting the participation in a clinical trial, based on the elegible patients identified from investigators database.	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]	53 completed trials between 2008 and 2012 50 ongoing trials (for further details, see website http://www.fsjd.org/en/hsjd-trials_40621)	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	1	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: 17 completed and 13 ongoing Proportion of all studies: 21%	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	9	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.6 Number of paediatric conditions covered by paediatric trials	13	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	68	For example, epidemiological studies,

1.1 Number of completed trials [M] Number of ongoing trials [M]	53 completed trials between 2008 and 2012 50 ongoing trials (for further details, see website http://www.fsjd.org/en/hsjd-trials_40621)	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 studies / programs		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: 21% Proportion of budget: 3.283.491,42 €	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)	399 patient included in investigator initiated studies	
Industry-sponsored trials	---	
1.10 Number of ongoing and completed trials	49 completed, 37 ongoing	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	22	Count specialities, without repetition, across all ongoing or completed paediatric trials
1.12 Number of paediatric conditions covered by paediatric trials	43	If not all areas within one speciality covered count conditions, without repetition, across all

1.1 Number of completed trials [M] Number of ongoing trials [M]	53 completed trials between 2008 and 2012 50 ongoing trials (for further details, see website http://www.fsjd.org/en/hsjd-trials_40621)	Any interventional clinical trial, whether non-commercial, investigator-initiated, industry-sponsored or commercial, in which the reporting party actively took part. Minimum requirement ([M]): one ongoing or one completed trial.
		ongoing or completed paediatric trials
1.13 Number of registered study participants (all studies)	168 patients in industry-sponsored trials	

Criterion 2: Network organisation and processes

2.1 Existence of an identified contact person for external enquiries [M]	☒ Yes ☐ No Comments: Joana Claverol Clinical Research Unit Manager Tel. +34 610 58 14 29 jclaverol@fsjd.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: There is an Internal research steering committe who reviews and approves all research studies conducted in the institution, regardless interventional or not.The primary mission of the Research Committee of the Hospital Sant Joan de Deu is to stimulate , monitor and guide the research in the Hospital. Objectives Approve and monitor the main research areas of the hospital. Define the rules, and classify scientific publications made in the hospital. Suggest infrastructure: facilities, equipment, administrative and computer support for research. Establish dissemination channels of research conducted by the hospital. Provide updated information on grants from public and private agencies. Assess and monitor the awards and research grants sponsored by the hospital. Report and validate economic grant applications for research Encourage the development of specific research subcommittees in different areas and hospital services. Members are:	Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).

	Dr. Jaume Pérez Payarols (President) Dr. Asteria Albert Cazalla Dr. Rafael Artuch Iriberri Prof. Jaume Campistol Plana Dr. Carmen de Torres Gómez-Pallete Dr. Ruben Díaz Nadari Dr. Clàudia Fortuny Guasch Dr. Alfredo García-Alix Dr. Àngels García Caazorla Dr. Maria Dolores Gómez Roig Dr. Lourdes Ibáñez Toda Dr. Carmen Muñoz-Almagro Mrs. Maite López Secanella http://www.hsjdbcn.org/Controller?_fb=tsch&_fp=0&pAction=_factory&lang=es&idPortlet=5066	
2.3 Existence of an external advisory / steering committee directing the reporting party [M]	☒ Yes ☐ No Comments: For R&D questions , for educational purposes, etc... Committee members are: Dr. Mara Dierssen Soto, Center for Genomic Regulation in Barcelona. Abizanda Dr. Isidre Ferrer, Director of the Institute of Neuropathology, University Hospital of Bellvitge. Dr. Guillem López Casasnovas, Dean of the Faculty of Economics and Business, University Pompeu Fabra. Dr. Jaume Marrugat , Director of Program Research Group Cardiovascular Epidemiology and Genetics IMIM. Dr. Romà Pallarés Giner, Deputy Director of the General Directorate of the Institute of Biomedical Research of Bellvitge (IDIBELL). Dr. Joan Pons Ràfols, Information Agency, Health Assessment and quality. Generalitat de Catalunya. Dr. Octavi Quintana Trias, Director of the European Research Area ERA (European Research Area) European Comission. Dr. José Luis Vázquez Barquero, Professor of Psychiatry at the	Minimum requirement ([M]): either an internal steering committee (2.2) or an external advisory / steering committee (2.3).

	University of Cantabria. Dr. Montserrat Vendrell, Director General of BIOCAT. Public website:http://www.fsjd.org/es/patronato-y-consejo-cient%C3%ADfico-asesor_2622	
2.4 Existence of a website	☐ Yes ☐ No Comments: www.hsjdbcn.org www.fsjd.org	If available, mention in "identification" above
2.5 Existence of newsletter	☒ Yes ☐ No Comments: Included in the webside portal	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 Clinical history is electronic and all patient's information is filed in the system. This database is only accessible for authorized users. Information can be downloaded for disease and condition and priovided externally if requested with no personal data included.	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: There is a declarated research data base to the Data Protection Agency with data of all subjects participating in clinical trials. Subjects are informed of the existence of said database when they sign the Informed Consent.The fullfilling of data protection according to applicable local regulations is also registered in the trial agreement signed between the institution and the sponsor.The database is not public . There are different levels of access (data entry, physicians, and/or study coordinators) with a unique ID and password.	Are provisions in place to ascertain patients' /study participants' data protection and data safety within network
2.8 Procedure(s) to access the database by third parties	☐ Yes ☒ No Comments:	Are provisions in place that data can be shared for planning, conducting or

		analysing a trial(s)?
2.9 Access to external databases /registries	☒ Yes ☐ No Comments: For some rare diseases there are external databases where the professionals of our organisation can access and are currently registering cases, such as: -European Network for Research on Alternating Hemiplegia -Metabolic diseases database -Neurotransmissor diseases registry -CVA -phenylketonuria registry -European Pediatric network in Diabetes and endocrinology (the national coordinator is from our hospital) -National Registry of Childhood tumours -Primary Immunogenicity registry (REDIP for national and ESID for international registry) -Eurofever - international systemic scleroderma registry - PHARMACHILD -PRINTO -PENTA...	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)	Number of peer-reviewed publications: • Total 641 • 2012: 153 (up to october) • 2011: 154 • 2010: 120 • 2009: 126 • 2008: 88 see attached document for references Authors from the organization	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	17	Grants obtained by reporting party (exclusively or not).
3.3 Access to expert groups M	☒ Yes ☐ No Comments: Many of our investigators belong to different expert groups such us PRINTO, PENTA FOUNDATION, International Oncology groups and many others at international and national level	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: All information is gathered in the Clinical Research Unit web site and for any question related to clinical trials the single point of contact is the Clinical Research Unit Manager.There is an e-mail address in the website to contact the clinical research unita manager:http://www.fsjd.org/en/clinical-research-unit_40359 Joana Claverol coordinador.URC@fsjd.org Direct phone:+34 610 58 14 29 mobile +34 610 58 14 29	Indicate if coordinated capacity (staff, process) is available to answer external scientific questions in relation to clinical trials during daily business.

3.1 Number of peer-reviewed publications in the last 5 years Provide exact reference(s) Describe the network's contribution to publication(s)	Number of peer-reviewed publications: • Total 641 • 2012: 153 (up to october) • 2011: 154 • 2010: 120 • 2009: 126 • 2008: 88 see attached document for references Authors from the organization	The publications should indicate that they are related to and reference the reporting party.
Standardized procedures for assessment of:	---	
3.5 Site feasibility	☒ Yes ☐ No Comments: For each trial the investigator performs the feasibility along with the Clinical research unit Manager.There is an SOP describing the process and the specific topics to be addressed by the sponsor and the institution.	This concerns the suitability of a site for conducting a given trial
3.6 Participant recruitment	☒ Yes ☐ No Comments: Yes, we follow recruitment indicators on a monthly basis and track all clinical trials activity	This concerns provisions to regularly monitor recruitment progress for a trial.
3.7 Budget calculation for studies	☒ Yes ☐ No Comments: The clinical research manager is responsible for budget review and negotiation (in case of industry-sponored clinical trials) and budget estimation in case of investigator's sponsored trials. There is a SOP describing the process.	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: Statement included in the institution contract agreement, signed by the Principal Investigator, the Research Foundation Director and the Hospital Director.All research staff actively participating in CT are trained on GCP. GCP training certificate available for sponsors if requested.GSP training tracking list is part of one Clinical Research Unit SOPs. SOPs based on GCP and applicable local regulations.Clinical satff training provided before particiapating in a clinical trial.For team members already trained, refreshment session every 2 years is mandatory.	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: Our EC is a pediatric EC accreditated by the competent authority and these considerations are the basis for all ethical discussions included in the EC review process. Statement from the EC related to the EnprEMA clarifications: 1-Accreditation from the competent authority (in co-official language) attached 2-EC board (showing the represented pediatric specialities) attached 3- 7 Members of the EC have a degree in Bioethics 4-SOPs approved by the local competent authority (in co-official language) attached 5-The EC is aware of the Ethical considerations for clinical trials on medicinal products conducted with the paediatric population, final version 2008, and enforces its compliance. Minutes after each meeting are not	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".

	publicly available but might be disclosed upon request. The Secretary of the EC is member of the European Forum for Good Clinical practise.	
4.3 Documented adherence to ethical considerations	☒ Yes ☐ No Comments: Our institution has an independent pediatric EC who is responsible for review and approval of all research projects conducted in pediatric population. Before submitting the projects into this independent committee, the internal Research committee has also evaluated the research studies to be conducted.	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 • SOP 0.1: Preparation, approval, distribution and review of Standard Operating Procedures for Clinical Trials Unit • SOP 1.1: Description of the Clinical Trials Unit • SOP 1.2 Equipment of Clinical Trials Unit, maintenance and periodic validation of the material and devices • SOP 1.3 Human Resources of the Clinical Trials Unit • SOP 2.1: Procedure for collection and reporting of adverse events • SOP 2.2: Procedures for medical emergency • SOP 2.3: Evacuation of the Clinical Trials Unit in non medical emergencies • SOP 3.1 Handling, storage and shipment of biological samples • SOP 4.1 Collection and Signature of the Informed Consent • SOP 5.1: Management of study medication in the Clinical Trial's Unit • SOP 6.1: Monitoring, audits and inspections	Indicate existence of SOP e.g. for study management, adverse events reporting etc.
4.5	☐ Yes ☒ No	Indicate if the reporting

Capacity to monitor studies (academic trials, industry sponsored trials) M	Comments: We contract an external CRO to perform the monitoring activities fullfilling ICH6	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: External service provided by a CRO	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: External service provided by a CRO	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: All clinical trials are submitted to our Regulatory Agency for reviewing and approval. Annual and final reports sent on a periodic basis. SAEs and safety information also reported. All clinical trials are conducted under the applicable regulations, stated in the site contract agreement	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: At regional level: Servei Català de la Salut; At National level : Ministry of Health. Development of Clinical Practice Guidelines and experts committee.	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 all clinical trials: Selection site meeting Pre-study meeting Initiation meeting Investigators meeting	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: GCP training for investigators and clinical Research Unit staff Audit training Clinical Research Unit SOPs training	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: Start-up training for all conducted clinical trials, driven by the sponsor. GCP trainings for all investigators GCP and IATA training for all clinical research unit staff	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:	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: Parent's organisation have an specific role in our hospital, with a meeting room available for them, where they can meet with other members and other organisations. Our Institution works very closely with parent's organizations to proactively look for clinical trials for their diseases, discussing the upcoming projects and the possibility to find potential candidates through the affiliated members.	Indicate if public stakeholders are /have been involved