



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2018 annual workshop of the European network of paediatric research at EMA





European network of paediatric research
at the European Medicines Agency



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Agenda of the 2018 annual workshop of the European network of paediatric research at the EMA (Enpr-EMA)

Date: Thursday 7 June 2018, room 03-A

Chairpersons: Mark Turner / Irmgard Eichler

Item	Agenda	Topic leader	Action	Time
09:00	Arrival and registration			30'
09:30	Welcome address	Enrica Alteri		5'
09:35	Session 1 Update on Enpr-EMA activities	Mark Turner Irmgard Eichler		
09:35	Report from the coordinating group (CG) Update on Enpr-EMA activities, achievements and challenges	Mark Turner	For information	20'
09.55	Session 2 Update on the Enpr-EMA Working Groups	Mark Turner		
09.55	Feedback from each Working Group on their completed actions, deliverables and identification of follow-on action plans: <ul style="list-style-type: none"> • WG on GCP Training • WG on Ethics • WG Young People advisory groups • WG on trial preparedness • WG interaction network-industry-regulators 	Working Group Chair Persons Gareth Veal Pirkko Lepola Pameal Dicks/ Begonya Nafria/ Segolene Gaillard Angeliki Siapkara Sue Tansey	For discussion	75'
11.10	Update on networks: <u>European networks:</u>		For discussion	60'

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Item	Agenda	Topic leader	Action	Time
	<ul style="list-style-type: none"> • TEDDY and EPTRI (European Paediatric Translational Research Infrastructure) • European Child & Adolescent Psychopharmacology Network –ECAPN • EAPRASnet (European Academy of Paediatrics Research in Ambulatory Settings network) • Central European Pediatric Oncology Early Trials Alliance (CEPOETA) <p><u>North American network:</u></p> <ul style="list-style-type: none"> • Duke Clinical Research Institute • Institute for Advanced Clinical Trials for Children (I-ACT for Children) 	<p>Adriana Ceci / Donato Bonifazi</p> <p>Alessandro Zuddas</p> <p>Adamos Hadjipanayis</p> <p>Regina Demlova</p> <p>Christoph Hornik</p> <p>Collin Hovinga</p>		
12.10	Update on implementation of CTR	Janson Lang Ann Marie	For information	15'
12.25	Lunch			60'
13.30	Session 3 Holistic approach to paediatric research Perspective of various stakeholders	Mark Turner	For discussion	
	Young people advisory and patient groups	Jennifer Preston		7'
	Industry	Taube Tillmann, Lene Rose Arfelt Martine Dehlinger-Kremer		7'
	Paediatric Clinical Trial Networks	Nicola Ruperto		7'
	European Reference Networks	Luca Sangiorgi		7'
	European Society for Paediatric Research	Karel Allegaert		7'
	Regulators	Gunter Egger, Ralph Bax		7'
	Clinical Trial Facilitation Group	Janson Lang Ann Marie		7'
	Health technology assessment bodies	Yvonne Schmidt		7'
	Ethics committees	Maria Alexandra Ribeiro		7'
	Example for multi-stakeholder collaboration: Global strategies for pulmonary arterial hypertension in children	Cecile Ollivier		10'

Item	Agenda	Topic leader	Action	Time
15.15	Coffee break			15'
15.30	General discussion How to avoid duplication/ ensure synergies of various organisations How to allow good communication How to divide the work between groups Challenges of clinical trials in (ultra) rare diseases	All		60'
16.30	Action points and conclusions	Mark Turner		15'
16.45	End of workshop			



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List of speakers / chairpersons

Surname	Name	Affiliation
Allegaert	Karel	European Society for Paediatric Research
Alteri	Enrica	European Medicines Agency (EMA), EU
Arfelt	Lene Rose	Tesaro Representing the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
Bax	Ralph	European Medicines Agency (EMA), EU
Bonifazi	Donato	TEDDY - European Network of Excellence for Paediatric Clinical Research experience.
Ceci	Adriana	TEDDY - European Network of Excellence for Paediatric Clinical Research experience.
Demlova	Regina	Central European Pediatric Oncology Early Trials Alliance (CEPOETA)
Dicks	Pamela	Chair of WG on YPAG ScotCRN, UK
Egger	Gunter	European Medicines Agency (EMA), EU
Eichler	Irmgard	Co-Chair of Enpr-EMA European Medicines Agency (EMA), EU
Gaillard	Segolene	Hospices Civils de Lyon/INSERM; European Young Persons Advisory Group Network (EYPAG-net)
Giaquinto	Carlo	PENTA
Hadjipanayis	Adamos	EAPRASnet (European Academy of Paediatrics Research in Ambulatory Settings network)
Hovinga	Collin	Institute for Advanced Clinical Trials for Children (I-ACT for Children)
Hornik	Christoph	Duke Clinical Research Institute
Janson Lang	Ann Marie	Swedish Medical Products Agency and Clinical Trial Facilitation Group
Lepola	Pirkko	FINPEDMED, FIN Chair of WG on Ethics
Nafria	Begonya	Institut de Recerca Sant Joan de Déu (Barcelona); European Young Persons Advisory Group Network (EYPAG-net)
Ollivier	Cecile	European Medicines Agency (EMA), EU
Ribeiro	Maria Alexandra	National Ethics Committee for Clinical Research (Portugal)
Ruperto	Nicola	Istituto G. Gaslini, Genova; PRINTO

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Surname	Name	Affiliation
Sangiorgi	Luca	Istituto Ortopedico Rizzoli, Italy; European Reference Networks (ENR)
Schmidt	Yvonne	Federal Joint Committee, Germany; European network for health technology assessment (EUnetHTA)
Seren	Cristina	Spanish Paediatric Clinical Trials Network (RECLIP)
Preston	Jennifer	University Liverpool; European Young Persons Advisory Group Network (EYPAG-net)
Siapkara	Angeliki	Medicines & Healthcare products Regulatory Agency, UK PDCO representative in Enpr-EMA
Taube	Tillmann	Boehringer-Ingelheim Representing the European Federation of Pharmaceutical Industries and Associations (EFPIA)
Turner	Mark	Chair of Enpr-EMA NIHR-CRN: Children, UK
Veal	Gareth	Chair of WG on Training Newcastle CCLG Pharmacology Studies Group, UK
Zuddas	Alessandro	ECANP (Child & Adolescent Neuropsychopharmacology Network)



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Coordinating Group: list of members

Affiliation	Representative
European Cystic Fibrosis Society – Clinical Trials Network (ECFS-CTN)	Tim Lee
EBMT European Blood and Marrow Transplantation - PDWP Paediatric Diseases Working Party as subgroup of the organisation	Christina Peters
European Network for Hyperkinetic Disorders (EUNETHYDIS)	Ian C K Wong
Finnish Investigators Network for Pediatric Medicines (FINPedMed)	Pirkko Lepola
German Neonatal Network (GNN)	Wolfgang Göpel
Innovative Therapies for Children with Cancer (ITCC)	Gilles Vassal
International Berlin/Frankfurt/ Münster Study Group (I-BFMSG)	Carmelo Rizzari
Family Pediatricians-Medicines for Children Research Network (FP-MCRN) - ONLUS	Ettore Napoleone
Medicines for Children Research Organisation Austria (OKIDS)	Ruth Ladenstein
PEDMED-NL	Saskia de Wildt
National Institute for Health Research Clinical Research Network-Children (NIHR CRN-Children)	Mark Turner Chair
Newcastle Children's Cancer and Leukaemia Pharmacology Studies Group (Newcastle-CCLG)	Gareth Veal

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Affiliation	Representative
Paediatric European Network for the Treatment of AIDS (PENTA)	Theoklis Zaoutis
Paediatric Investigation Into Health Products Network (RIPPS)	Behrouz Kassai-Koupai
Pediatric Rheumatology International Trials Organisation (PRINTO)	Nicolino Ruperto
Scottish Medicines for Children Network (scotcrn)	Pamela Dicks
United Kingdom Paediatric Vaccines Group (UKPVG)	Paul Heath
Red de Investigación Traslacional en Infectología Pediátrica (RITIP)	Cristina Calvo
PDCO Member (1)	Marek Migdal
PDCO Member (2)	Angeliki Siapkara
Patient representative	Jose Drabwell
Healthcare professionals representative	Adamos Hadjipanayis
Networks with observer status¹	
Mother Infant Child Youth Research Network (MICYRN)	Thierry Lacaze
Duke Clinical Research Institute	Christoph Hornik
Industry associations with observer status¹	
EFPIA	Tillmann Taube
EUCOPE	John Watson
EUCROF	Martine Dehlinger-Kremer
Other observers¹	
European Reference Networks	Luca Sangiorgi

¹ Observers have the right to speak but not to vote.



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List of Working Groups:

Joint working group on public-private partnership

Working group volunteers: **Susan Tansey**, Pirkko Lepola, Pamela Dicks, Martine Dehlinger-Kremer, Jenny Preston, Stefanie Breitenstein, Enrico Bosone, Chris Walker, Colin Hayward

Working group on Ethics

Working group volunteers: **Pirkko Lepola**, Jo Mendum, Peter Salabank, David Neubauer, Adriana Ceci, Viviana Giannuzzi, Heidi Glosli, Martine Dehlinger-Kremer, Diane Hoffman.

Working group on Young patient advisory groups

Working group volunteers: **Pamela Dicks**, Segolene Gaillard, Begonya Nafria, Joanna Claverol, Anne Junker, Jenny Preston, Gareth Veal, Veerle Buteel.

Working group on GCP training across multispecialty and countries

Working group volunteers: **Gareth Veal**, Pirkko Lepola, Segolene Gaillard, Mary Costello, Susan Macfarlane, Adriana Ceci, Florence Bosco

Working Group on trial preparedness

Working group volunteers: **Angeliki Siapkara**, Ruth Ladenstein, Mark Turner, Joana Claverol Torres, Ann Marie Janson Lang, Donato Bonifazi, Segolene Galliard, Geraldine Boylen, Carmelo Rizzari, Samantha Scarlett, Cristina Seren Trasorras, Dimitrios Athanasiou, Siri Wang, James Barnes, Claudio Fracasso, Ensio Norjavaara, Tillmann Taube, Notelet Loic, Sabine Scherer, Marek Migdal, Nicola Ruperto, Ivan Foeldvari., Margaret Patton, Niyati Prasad, Gunter Egger, Roberto de Lisa





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Enpr-EMA networks update 2017-2018

Duke Clinical Research Institute (DCRI) (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Neonatology, infectious diseases, critical care, cardiology, nephrology, neurology, gastroenterology, dermatology, psychiatry, pharmacology, maternal health and lactation
Countries involved	US, Canada, Singapore, Israel, United Kingdom
Number of clinical trials conducted	>25
Publications (please add links to external sources when possible)	https://www.pediatrictrials.org/published-results-presentations-and-articles-of-interest/
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	<p>Training: >25 total fellows 4 active fellows in training (T32, foundation, and institutional funding) 3 active junior faculty with NIH K-23 funding</p> <p>Collaboration: <i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development US Food and Drug Administration Other US research networks</p> <p>Clinical Studies (non-trials): -meta-analyses -electronic health record data -retrospective analyses</p>
Public involvement	<p>Patient Advocate Review of Study Protocols and Informed Consent Forms</p> <p>New partnership with iCAN research</p>



European Cystic Fibrosis Society – Clinical Trials Network (ECFS-CTN) (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Cystic Fibrosis
Countries involved	Belgium, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Poland, Portugal, Spain, Sweden, Switzerland, The Netherlands, UK
Number of clinical trials conducted	From April 2017 to March 2018: 30 clinical trials were active in the network (all ages)
Publications (please add links to external sources when possible)	In press: JoVE (Journal of Visualised Experiments) George M. Solomon, Inez Bronsveld, Kathryn Hayes, Michael Wilschanski, Steven M. Rowe, and Isabelle Sermet-Gaudelus. Standardized Measurement of Nasal Membrane Transepithelial Potential Difference (NPD).
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	<p><u>Yearly training day for investigators and research coordinators</u> Seville, 07Jun2017</p> <p><u>Quality</u> A dedicated quality manager evaluates site performance metrics for study startup and enrolment. Sites are receiving detailed, individualized evaluation reports. Less performing sites entered a coaching program.</p> <p><u>More focus on phase 1 trials</u> As more phase 1 trials are presented to the network, these protocols are now also reviewed by protocol review committee and more closely discussed with pharma</p> <p><u>Preparation next network expansion:</u> announcement June 2018</p> <p><u>"Additional Research Capacity" (ARC) program:</u> supporting more research personal at sites to increase the network capacity to run trials</p> <p><u>Partnering EU projects:</u> PRO-CF-MED (H2020 No. 633545) https://cordis.europa.eu/project/rcn/193242_en.html HIT-CF (H2020 No.755021) https://www.hitcf.org/ OligoGpivotalCF (H2020 No. 755234) http://algipharma.com/wp/wp-content/uploads/2018/01/EU-grant-Press-release-20-1-2018.pdf 1 IMI2 project in setup related to pediatric trials ERN-LUNG http://ern-lung.eu/</p>

Public involvement	Continuous close collaboration with national and European patient organizations. There is a CF patient organisation representative on our CTN Executive Committee which meets every 2 weeks by teleconference, as well as multiple European national CF patient organisations represented on our CTN steering committee which meets twice yearly face-to-face. Every protocol review we undertake includes 2 CF adults or parents of a CF child as co-reviewers. In addition we are working to initiate a YPAG initiative, already produce patient friendly activity reports, recommend patient reported CF specific outcome measures, agree patient referral policies, and continually take note of patient priorities in our decision making as a network.
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EUNETHYDIS - Germany (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	ADHD, aggression, autism spectrum disorders, Tic disorders psychopharmacology, neurophysiology, neuropsychology
Countries involved	Germany
Number of clinical trials conducted	about 10 (including German PI for European multisite licensing trial for Vyvanse (Shire))
Publications (please add links to external sources when possible)	https://www.ncbi.nlm.nih.gov/pubmed/?term=banaschewski+tobias
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	<p>Delivery of training in child and adolescent psychopharmacology as a member of the faculty of the child and adolescent section of the European College of Neuropsychopharmacology (ECNP) in Europe</p> <p>EU FP7: Aggression subtyping for improved insight and treatment innovation in paediatric psychiatric disorders (AGGRESSOTYPE) (2013-2018).</p> <p>EU FP7: High callous-unemotional traits and aggression (MATRICS) (2013-2018).</p> <p>EU-AIMS, Innovative Medicines Initiative EU grant (2012-2018).</p> <p>Kings-College, London: IMAGEN project follow-up (2007-2020)</p> <p>German Federal Ministry of Education and Research: Research Network ESCALIFE (2015-2020)</p>
Public involvement	<p>President of the German Society of Child & Adolescent Psychiatry (Jan 2016 – Dez 2017), since Jan 2018 Past-President</p> <p>Member of the Directory Board of the German ADHD network</p> <p>Advisory Board of ADHD Europe</p>

EUNETHYDIS – UK and Spain (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Pharmacology, evidence synthesis
Countries involved	UK and Spain
Number of clinical trials conducted	1 (co-investigator)
Publications (please add links to external sources when possible)	https://www.ncbi.nlm.nih.gov/pubmed/?term=cortese+samuele
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Delivery of training in child and adolescent mental health as a member of the board of the Association for Child and Adolescent Mental health (ACAMH) in the UK Delivery of training in child and adolescent psychopharmacology as a member of the faculty of the child and adolescent section of the British Association of Psychopharmacology (BAP) in the UK Delivery of training in child and adolescent psychopharmacology as a member of the faculty of the child and adolescent section of the European College of Neuropsychopharmacology (ECNP) in Europe
Public involvement	-

FINPEDMED (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	All subspecialties in paediatrics + clinical pharmacology + biomedical ethics + rare diseases + formulation (medicinal products) + pharmacogenetics + clinical neurophysiology (neonates)
Countries involved	1 + 4 (Sweden, Norway, Iceland, Norway)
Number of clinical trials conducted	Academic + sponsored: 26 in Finland.
Publications (please add links to external sources when possible)	none.
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Training: 01-03/2017; 2 tailored Paediatric Clinical Research courses for Paediatric Nurses (2x4 Credit Units), 2 nd Nordic Conference on Paediatric Medicines (05/2018), 3 rd National Congress on Paediatric Medicines (09/2018). Consultations: 4 Expert Consultations (PIPs/trial protocol/disease/condition).
Public involvement	none.

FP-MCRN (Family Pediatricians-Medicines for Children Research Network) (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	PAS Studies- Epidemiology – Infectious Diseases -
Countries involved	Italy
Number of clinical trials conducted	2
Publications (please add links to external sources when possible)	N. 5 independent publications
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Training courses on Prescriptive appropriateness of drugs (Antibiotics and Inhaled Steroids) Training course on Pediatric Pharmacovigilance
Public involvement	Family Communication: Families can certainly give excellent advice and practical suggestions on the priorities for clinical trials in children

International BFM Study Group (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Pediatric Hamtological Malignancies
Countries involved	1. Europe <ul style="list-style-type: none"> • Austria (BFM-A) • Belgium (CLCG-EORTC) • Croatia • Czech Republic (CPH) • Denmark (NOPHO) • Finland (NOPHO) • France (SFCE) • Germany (BFM-G) • Greece (HeSPHO) • Hungary (HPOG) • Iceland (NOPHO) • Italy (AIEOP) • Norway (NOPHO) • Poland (PPLLSG) • Serbia and Montenegro • Slovakia • Slovenia • Spain • Sweden (NOPHO) • Switzerland (BFM-CH)

	<ul style="list-style-type: none"> • The Netherlands (DCOG) • Turkey • Unit. Kingdom (UKCCLG) • Ukraine <p>2. Outside Europe</p> <ul style="list-style-type: none"> • Argentina (GATLA, SAHOP) • Australia and New Zealand (ANZCHOG) • Chile (PINDA) • Hong-Kong • Israel (INS) • Japan (JPLSG) • Uruguay
Number of clinical trials conducted	14
Publications (please add links to external sources when possible)	See Annex 1
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	<p>1. Continuous education through the organization of the Annual Meeting (> 300 participants), several Committees meetings and a Biannual Congress on Childhood Leukemias.</p> <p>2. Promote the cooperation with countries with limited resources through the organization of international clinical studies.</p>
Public involvement	Interaction with EMA, ASH, SIOPE, ICCCP and additional national scientific societies, regulatory boards, and disease related international groups.

ITCC (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Paediatric oncology; pharmacology; biology; early drug development
Countries involved	56 centres in 14 countries
Number of clinical trials conducted	23 ongoing clinical trials in 2017 (phase 1, 1/ 2 and 2 trials)
Publications (please add links to external sources when possible)	<p>http://www.itcc-consortium.org/scripts/files/591eee7776c983.40402275/nrciinonc-2017-59.pdf</p> <p>http://www.itcc-consortium.org/scripts/files/5a3793c3cbf200.31195221/10-1007_s11060-017-2698-z.pdf</p> <p>http://www.itcc-consortium.org/scripts/files/5a9967555a1986.00123720/10-year-reort-on-the-european-paediatric-regulation-and-its-</p>

	impact-on-new-drugs-for-children-s-cancers-1.pdf https://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045(17)30442-4.pdf and all publications for individual trials
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	ITCC is founding member of the Accelerate Platform initiative (www.accelerate-platform.eu) and a member of the ITCC P4 IMI2 paediatric preclinical proof of concept project (www.itccp4.eu)
Public involvement	Parents gathering into a Charity asked to review the protocol of all academia-sponsored trials as well as information package of both industry and academia sponsored trials; partnership with the Parents Association Imagine for Margo (www.imagineformargo.org). Parents are partners of the EU project that are submitted, when clinical research activity is part of the proposal.

Newcastle Children's Cancer and Leukaemia Pharmacology Studies Group (Newcastle-CCLG) (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Pharmacology Oncology
Countries involved	UK
Number of clinical trials conducted	6 ongoing paediatric clinical pharmacology trials
Publications (please add links to external sources when possible)	<p>1. White-Koning, M, Osborne, C, Paci, A, Boddy, AVB, Chatelut, E, Veal, GJ. Investigating the potential impact of dose-banding for systemic anti-cancer therapy (SACT) in the paediatric setting based on pharmacokinetic evidence. Eur J Cancer 2018 91: 56-67 (https://www.sciencedirect.com/science/article/pii/S0959804917314594?via%3Dihub)</p> <p>2. Veal, GJ, Malik, S, Lupo, M, MacFarlane, S, Lepola, P, Costello, M, Ceci, A, Boué, C, Lecour, L, Otto, A, Rastegari, M, Berry, P. Investigating the roles and training of paediatric research nurses working across Europe - a questionnaire-based survey. BMJ Paediatrics Open 2017 1: e00170 1-7 (http://bmjpaedsopen.bmj.com/content/1/1/e000170)</p> <p>3. Vormoor, B, Veal, GJ, Griffin, MJ, Boddy, AV, Irving, J, Minto, L, Case, M, Banerji, U, Swales, KE, Tall, JR, Moore, AS, Toguchi, M, Acton, G, Dyer, K, Schwab, C, Harrison, CJ, Grainger, JD, Lancaster, D, Kearns, P, Hargrave, D, Vormoor, J. A Phase I/II trial of AT9283, a selective inhibitor of aurora kinase in children with relapsed or refractory acute leukaemia:</p>

	challenges to run early phase clinical trials for children with leukaemia. Ped Blood Cancer 2017 64: e26351 (https://onlinelibrary.wiley.com/doi/abs/10.1002/pbc.26351)
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Clinical trial data generated by the group have been presented at the following international meetings: <ol style="list-style-type: none"> 1. 109th Annual Meeting of the AACR, Chicago, USA (April, 2018) 2. 59th American Society of Hematology Annual Meeting, Atlanta, USA (December, 2017) 3. 15th International Congress of Therapeutic Drug Monitoring & Clinical Toxicology, Kyoto, Japan (September, 2017) 4. Children with Cancer UK Childhood Cancer 2017 Meeting, Newcastle (September, 2017) 5. 2nd National Symposium on Therapeutic Drug Monitoring, Vellore, India (July, 2017)
Public involvement	Worked with the patient advocacy group PORT in relation to a new clinical 'therapeutic drug monitoring' registry study relating to clinical pharmacology data in neonates and other hard to treat patient groups which will start in 2018 (successful grant application made to the NIHR Research for Patient Benefit funding stream).

Pediatric Rheumatology International Trials Organisation (PRINTO) (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Pediatric Rheumatology and Auto-inflammatory Diseases
Countries involved	About 90 countries
Number of clinical trials conducted	6 on-going sponsored clinical trials See also: https://www.printo.it/projects/ongoing
Publications (please add links to external sources when possible)	https://www.printo.it/publications/papers
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	International coordinating centre for clinical trials/studies Training of foreign physicians (around 20 per year) Consultation with pharmaceutical companies (for trials planning, centre selection, data collection, data analysis and interpretation, and data reporting)
Public involvement	Patient's and parent's organisations have been identified through a specific project funded by the European Union that allowed the creation of a website for families available on more than 50 languages (www.pediatric-rheumatology.printo.it). In addition, organisations are invited to attend the annual PRINTO workshop held each year at the PRES scientific

meeting.
 PRINTO also collaborates with Italian Ministry of Health, the Italian Agency for Drugs (AIFA), European Commission.

PEDMED-NL (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	General Paediatrics Benign Haematology Cardiology Diabetes & Endocrinology IC & pain Infectious diseases Psychiatry Gastroenterology and nutrition Metabolic diseases Nephrology Neonatology Neurology Oncology Respiratory diseases Rheumatology and inflammatory diseases Pharmacology Dermatology
Countries involved	1 (The Netherlands)
Number of clinical trials conducted	3 (EU FP7 funded projects)
Publications (please add links to external sources when possible)	PMID: 29105908
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Contact to connect companies with KoLs. Use the network to connect companies/investigators with potential sites to be involved in their study
Public involvement	-

PENTA-ID network (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Paediatrics, HIV, Infectious diseases
Countries involved	Portugal, Spain, France, Ireland, UK, Belgium, the

	Netherlands, Germany, Sweden, Denmark, Switzerland, Italy, Greece, Poland, Romania, Estonia, Lithuania, Ukraine, Russia, Turkey, Thailand, Uganda, South Africa, Brazil, Argentina, Mexico, Zimbabwe
Number of clinical trials conducted	12 completed + 3 ongoing
Publications (please add links to external sources when possible)	https://penta-id.org/category/publications/
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Training, observational studies, pharmacovigilance studies, participation in projects and networks (c4c, EPTRI)
Public involvement	Involvement of YPAG organisations, EMA-PDCO representation

RECLIP-Spanish Paediatric Clinical Trials Network (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	No changes.
Countries involved	No changes in terms of country. Only Spain involved. Number of participating sites has increased from 19 to 26 sites.
Number of clinical trials conducted	4 new clinical trials since April 2017: 3 ongoing clinical trials: Phase I - Gastroenterology Phase IIIb - Gastroenterology Phase II - Oncology 1 clinical trial in start-up phase: Phase I-IIA – Infectious Diseases
Publications (please add links to external sources when possible)	No new publications as a network issued.
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Sep2017- Jornada Presentación Guía Unidades Pediátricas Farmaindustria Nov2017- Interactive Infectious Diseases Workshop –TIPICO Jan2018- e-congress vacunas Apr2018- Jornada Vacunas para enfermería 2018 Apr2018- Semana Mundial de la inmunización May2018- Launching of Conect4Children initiative May2018- Junta de Presidentes de las Sociedades de

	Especialidades Junta de la Asociación Española de Pediatría.
Public involvement	Patient Advisory Board established after the first Annual Meeting of RECLIP, which took place on the 22 nd of January of 2018. Patient Advisory Group is made up by 5 members from Hospital Sant Joan de Deu, H.U. Niño Jesús, H.U. QuirónSalud, H.R. Materno-Infantil de Málaga.

RITIP (Translational Research Network in Pediatric Infectious Diseases) Enpr-EMA (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Infectious Diseases and Vaccines
Countries involved	Spain
Number of clinical trials conducted	4 RSV PED-002 BREATHHER/PENTA 16 SMILE/PENTA 17 ODYSSEY/PENTA 20
Publications (please add links to external sources when possible)	<ul style="list-style-type: none"> • https://www.ncbi.nlm.nih.gov/pubmed/?term=Dolutegravi+r+plus+abacavir%2Flamivudine+works+in+adolescents%2C+but+size+matters • https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5626255/ • https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5419921/ • https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5698448/?report=reader • https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5354294/?report=reader • https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5716580/?report=reader • https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5799169/?report=reader • https://www.ncbi.nlm.nih.gov/pubmed/29751940 • https://www.ncbi.nlm.nih.gov/pubmed/29705992 • https://www.ncbi.nlm.nih.gov/pubmed/?term=29374831 • https://www.ncbi.nlm.nih.gov/pubmed/?term=29575071 • https://www.ncbi.nlm.nih.gov/pubmed/?term=29374831 • https://www.ncbi.nlm.nih.gov/pubmed/?term=29424816 • https://www.ncbi.nlm.nih.gov/pubmed/?term=28978246
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	<p>RESEARCH PROJECTS:</p> <p>ENTEROGEN PROJECT: Evaluation of genetic factors in the susceptibility and prognosis of enterovirus infections.</p> <p>EDUCATION:</p> <p>JOURNEY OF PEDIATRIC INFECTIOUS DISEASES. H. Clínico Universitario. 15th June, 2017. Madrid.</p>

	<p>VI JOURNEY. VACCINES FOR EVERYBODY. 29-30th September. Hotel Reserva del Higuero. Fuengirola, Málaga</p> <p>MODERN TRENDS IN INFECTIOUS DISEASES AND IMMUNOLOGY. IV Training Course for Paediatric Infectious Diseases Trainees. Seville, 27-28th of October 2017</p> <p>8th INTERACTIVE INFECTIOUS DISEASE WORKSHOP. 23-24th November 2017. Santiago de Compostela. Spain. http://www.lasvacunascuentan.es</p> <p>I VIRTUAL CONFERENCE ON VACCINES. 15-19th January 2018. profesionales.msd.es</p> <p>VII JOURNEY OF TROPICAL PEDIATRIC INFECTIOUS DISEASES "New pathogens in childhood" 24th January 2018. Hospital Universitario La Paz. Madrid.</p> <p>IX MEETING SPANISH SOCIETY OF PEDIATRIC INFECTIOUS DISEASES. Sevilla 8-10th March 2018.</p> <p>INTERNATIONAL HEALTH COURSE. PROCSIS. Hospital Vall de Hebrón. February-June 2018.</p> <p>III NEUMOFORO. PNEUMONIA, FROM THE RISK TO THE SOLUTION. 13-14th April 2018. Universidad de Ciencias de la Salud. Alcorcón, Madrid.</p>
Public involvement	

TEDDY Network - European Network of Excellence for Paediatric Clinical Research (category 1)

Areas of expertise (e.g.: neonatology, haematology, pain, neurology, infectivology)	Multispecialty network (Specialties/ conditions covered: Haematology, Pain, Anesthesiology, Neurology, Neonatal Infections, Immunology, Infections, Iron overload, Pain in oncologic patients, Neuropathic pain, Sedation in PICU, Neonatal sepsis, Neonatal Meningitis, Epilepsy, Neurometabolic diseases, Clinical Pharmacology, Intensive care, Modelisation - PK, Neonatology, Pain Management, Pharmacovigilance, Psychiatry, psychology – Child Psychiatry, Psychiatry, psychology – Adolescent Psychiatry), Cystic Fibrosis, HIV, metabolic diseases.
Countries involved	Europe: Cyprus, Czech Republic, France, Germany, Greece, Italy, The Netherlands, Poland, Romania, Spain, Sweden, UK. Outside Europe: Albania, Australia, China, Egypt, Israel, Lebanon, Russia, Tunisia, Ukraine.
Number of clinical trials conducted	13 (5 completed and 8 ongoing)
Publications (please add links to external sources when possible)	<ul style="list-style-type: none"> http://bmjpaedsopen.bmj.com/content/1/1/e000170 https://www.ncbi.nlm.nih.gov/pubmed/28093642 http://www.intechopen.com/books/drug-discovery-and-development-from-molecules-to-medicine/clinical-trials-in-paediatrics-regulatory-and-methodological-aspects

	<ul style="list-style-type: none"> • https://www.ncbi.nlm.nih.gov/pubmed/26037896 • https://www.ncbi.nlm.nih.gov/pubmed/28301570 • https://www.ncbi.nlm.nih.gov/pubmed/28471975 • https://onlinelibrary.wiley.com/doi/abs/10.1111/apa.14373 • https://www.ncbi.nlm.nih.gov/pubmed/29206851 • https://www.ncbi.nlm.nih.gov/pubmed/28365283
<p>Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)</p>	<p>Participation in:</p> <ul style="list-style-type: none"> - Enpr-EMA pilot of the model for industry/network communication (May 2018) - Public consultation on “Concept paper paediatric addendum of the guideline on clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic disease” (January 2018) - Evaluation of the legislation on medicines for children and rare diseases (medicines for special populations): https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-6059807/feedback/F8758_en (January 2018). - EnprEMA Working Group for preparedness in paediatric clinical trials. In particular, TEDDY is participating in Action point 1 (Review the current regulatory guidance and academic publications in relation to the conduct of trials in the paediatric population to identify discussion on preparedness) and Action point 4 (Development of a prompt guide/questionnaire to be used in interviews and brainstorming sessions on trial preparedness with stakeholder groups) (October 2017 - ongoing) <p>For a full list of activities visit: www.teddynetwork.net</p>
<p>Public involvement</p>	<p>TEDDY has supported the Rare Disease Day 2018, that took place on February 28th, 2018, by becoming a friend of Rare Disease Day and showing its support on its official website and social networks.</p> <p>TEDDY has promoted the creation the first Young Patients Advisory Group in Italy (KIDS Bari), in June 2017, that is attending an annual training programme about biomedicine, research, clinical trials and innovation thanks to the involvement of a professional team of pharmacologists, pediatricians, child psychologists, investigators, research nurses and communication experts.</p> <p>TEDDY has launched the first Albanian YPAG in Tirana (KIDS Albania) in collaboration with CVBF Albania and the University Hospital Center Tirana “Mother Teresa”, Service of Paediatrics, in November 2017, in order to train the youths to be able to help researchers in trials design, prioritizing future researches, improving communication with the target population and increasing awareness on clinical research.</p>

OKIDS GmbH (category 1)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Adolescent medicine, Allergology, Cardiology, Cystic fibrosis, Dermatology, Endocrinology, Gastro-Enterology, General-Paediatrics, Haematology, Haemato-Oncology, Immunology, Infectious Diseases, Intensive Care, Metabolic Diseases, Neonatology, Nephrology, Neurology, Nutrition, Oncology, Ophthalmology, Palliative Care, Pneumology, Rheumatology,
Countries involved	Austria
Number of clinical trials conducted	a total of 166 supported studies, 52 conducted studies
Publications (please add links to external sources when possible)	
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	a total of 84 feasibilities / enquiries for trials GCP trainings
Public involvement	Collaboration with EUPATI 1 st OKIDS-EUPATI Congress – November 2017

RED SAMID (Maternal and Infant Health and development Spanish National Network) (category 2)

Areas of expertise (eg: neonatology, pharmacology, oncology)	NEONATOLOGY, PERINATOLOGY, Paediatrics, obstetrics, nutrition and metabolism, endocrinology, pediatric and neonatal intensive care and paediatric surgery
Countries involved	1 (SPAIN)
Number of clinical trials conducted	Number of completed trials: 8 Number of ongoing trials: 7
Publications (please add links to external sources when possible)	Included in attached document: Number of publications (YEAR 2017): 278 (See attached document) Number of publications (YEAR 2018): 82 (See attached document)
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Training courses received over the last year: 5 Sponsorship of courses organized in the last year by members of the research network: 7 Participation in other research studies: 15 Collaboration with the Institute of Health Carlos III (Spanish public institution of health research) in consultations and evaluation of projects and clinical trials Several of its PIs are actively involved in Ethics Committees Several research network groups are actively involved in steering committees of research consortia and in National and International

	Research Societies (ESPR, SPR, EAP)
Public involvement	Association of parents of premature infants (APREVAS, EFCNI) The EFCNI organisation is involved on the EuroNeoKiss trial. European Patients' Academy on Therapeutic Innovation (EUPATY SPAIN)

CEPOETA (category 3)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Paediatric oncology (multispecialty - the whole scope of pediatrics oncology and hemato-oncology, pediatric onco-pharmacology, surgery, rehabilitation, radiology)
Countries involved	Czech Republic, Slovakia, Poland, Hungary, Slovenia, Macedonia, Bulgaria, Serbia
Number of clinical trials conducted	2 clinical trials ongoing, in recruitment period (phase I/II, II)
Publications (please add links to external sources when possible)	<p>BERTHOLD Frank HÖMBERG Marc PROLESKOVSKAJA Inna MAZÁNEK Pavel BELOGUROVA Margarita ERNST Angela ŠTĚRBA Jaroslav Metronomic therapy has low toxicity and is as effective as current standard treatment for recurrent high-risk neuroblastoma. <i>Pediatric Hematology and Oncology</i>, 2018; 64:5</p> <p>CHLAPEK Petr SLÁVIKOVÁ Viera MAZÁNEK Pavel ŠTĚRBA Jaroslav VESELSKÁ Renata Why Differentiation Therapy Sometimes Fails: Molecular Mechanisms of Resistance to Retinoids <i>International Journal of Molecular Sciences</i>, 2018; 19: 1</p> <p>MORENO L. CARON H. GEOERGER B. EGGERT A. SCHLEIERMACHER G. BROCK P. VALTEAU-COUANET D. CHESLER L. SCHULTE J.H. DE PRETER K. MOLENAAR J. SCHRAMM A. EILERS M. VAN MAERKEN T. JOHNSEN J.I. GARRETT M. GEORGE S.L. TWEDDLE D.A. KOGNER P. BERTHOLD F. KOSTER J. BARONE G. TUCKER E.R. MARSHALL L. HEROLD R. ŠTĚRBA Jaroslav NORGA K. VASSAL G. PEARSON A.D.J. Accelerating drug development for neuroblastoma - New Drug Development Strategy: an Innovative Therapies for Children with Cancer, European Network for Cancer Research in Children and Adolescents and International Society of Paediatric Oncology Europe Neuroblastoma project. <i>EXPERT OPINION ON DRUG DISCOVERY</i>, 2017; 12: 8</p> <p>FĚDOROVÁ Lenka ZDRAŽILOVÁ DUBSKÁ Lenka PILÁTOVÁ Kateřina MÚDRY Peter MAZÁNEK Pavel PAVELKA Zdeněk HLAVÁČKOVÁ Eva ŠTĚRBA Jaroslav FLAJSAROVÁ Lucie DEMLOVÁ Regina VALÍK Dalibor Immunomonitoring of patients treated with personalized dendritic cell-based vaccine, Abstract , 2017</p>

Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	<p>CEPOETA ongoing clinical trials:</p> <p>Recurrent neuroblastoma and Ewing´s sarcoma: Treosulfan based high dose chemotherapy with autologus PBSC support (ReNETA study) EudraCT number: 2015-002584-41</p> <p>Combined antitumor therapy with ex vivo manipulated dendritic cells producing interleukin-12 in children, adolescents and young adults with progressive, recurrent or primarily metastatic high-risk tumors (KDO-DC1311) EudraCT number: 2014-003388-39</p> <p>Other research projects (grants):</p> <p>16-33209A Genome-wide expression profiling and mutation analysis as the diagnostic basis for personalized pediatric cancer treatment plans: a feasibility study – Ministry of Health CZ</p> <p>16-34083A Receptor tyrosin kinases and downstream signaling pathways as possible therapeutic targets in pediatric refractory solid tumors - Ministry of Health CZ</p> <p>CZ.1.05/2.1.00/03.0101 RECAMO (Regionální centrum aplikované molekulární onkologie) - Ministry of Education, Youth and Sports CZ</p>
Public involvement	<p>CEOPETA creates close collaboration with priority consumers, mainly patients and patients' groups in public health and health advocacy in CZ and across EU. Healthcare costs are increasing faster than the economy can currently keep up with. Thus, economic health-care considerations will feature prominently in the political discussions around health and healthcare reforms and patients and the patient community are called upon to play a more visible role than in the past. As the results of independent investigator-initiated trials are important part for this evidence-based discussion with policy makers and health-care providers, the CEPOETA with the primary aim to serve to the patient community can´t stand outside. The strategic plan for CEPOETA covers closer cooperation with patient´s groups including participation in research projects, regulatory and ethic discussion as well as education within field of clinical trials.</p>

NEO-CIRC (category 3)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Neonatology
Countries involved	UK, France, Germany, Hungary, Romania, Spain, Turkey, USA
Number of clinical trials conducted	1 drug related

Publications (please add links to external sources when possible)	http://www.neocirculation.eu/pubs.shtml
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Training in clinical drug trials, GCP, PK/PD studies, biomarkers Participation in International Neonatal Consortium (www.c-pathg.org) Completion of 6 clinical human studies related to circulatory adaptation after birth Completion of 1 animal study investigating the new age appropriate formulation
Public involvement	Through local parent fora, EFCNI officially affiliated (www.efcni.org)

NorPedMed (category 3)

Areas of expertise (eg: neonatology, pharmacology, oncology)	NorPedMed is a national multispecialty research network, i.e. covers all paediatric sub-specialities.
Countries involved	Norway
Number of clinical trials conducted	29 of which 5 were completed in 2017 and 24 are ongoing. 10 of the trials are academic trials. List of studies may be submitted if desired.
Publications (please add links to external sources when possible)	Publications (partly) funded by Medicines for Children Network Norway (MCNN), which NorPedMed is a part of: Nurses' Knowledge, Attitudes and Clinical Practice in Pediatric Postoperative Pain Management. Smeland AH, Twycross A, Lundeberg S, Rustøen T. Pain Manag Nurs. 2018 May 16. pii: S1524-9042(17)30426-5. doi: 10.1016/j.pmn.2018.04.006 The WE-Study: does botulinum toxin A make walking easier in children with cerebral palsy?: Study protocol for a randomized controlled trial. Brændvik SM, Roeleveld K, Andersen GL, Raftemo AE, Ramstad K, Majkic-Tajsic J, Lamvik T, Lund B, Follestad T, Vik T. Trials. 2017 Feb 6;18(1):58 A comparison of pain assessment by physicians, parents and children in an outpatient setting. Brudvik C, Moutte SD, Baste V, Morken T. Emerg Med J. 2017 Mar;34(3):138-144 Physical compatibility of total parenteral nutrition and drugs in Y-site administration to children from neonates to adolescents. Staven V, Iqbal H, Wang S, Grønlie I, Tho I. J Pharm Pharmacol. 2017 Apr;69(4):448-462

Paediatric European Digestive Diseases Clinical Research Network (PEDDCReN) (category 3)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Paediatric Gastroenterology, Hepatology and Nutrition
Countries involved	EU plus Israel - (23)
Number of clinical trials conducted	No intervention trials One pan-European prospective study of rare and severe complications of PIBD
Publications (please add links to external sources when possible)	X2 published abstracts at ESPGHAN 2018 (JPGN)
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	2018 Joined the Connecting 4 Children Network as the GHN link (includes liaising with ESPGHAN) 201 2017 Proposal for a pan-European pseudo-obstruction network. 2018 Working group meeting at ESPGHAN Annual Meeting (Geneva)
Public involvement	None

SwissPedNet (category 3)

Areas of expertise (eg: neonatology, pharmacology, oncology)	National network consisting of nine clinical paediatric hubs and two platforms (paediatric pharmacology and registries)
Countries involved	Switzerland
Number of clinical trials conducted	SwissPedNet is a research infrastructure and does not act as sponsor of clinical trials.
Publications (please add links to external sources when possible)	N.A.
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	SwissPedNet Translational & Clinical Research Session: 10 to 14 young researchers get the opportunity to present their work during a 10 minutes-talk and the ensuing dialogue with the audience. SwissPedNet together with the Swiss Society of Paediatrics launched a call in Paediatric health services research to fund one research project. NextGen Workshop: special research day to attract younger colleagues and provide practical first-hand information from senior researchers.

Public involvement	This is a topic of individual projects and not driven by the research infrastructure SwissPedNet.
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EAPRASnet (category 4)

Areas of expertise (eg: neonatology, pharmacology, oncology)	General paediatrics, Primary Care Pediatrics
Countries involved	40
Number of clinical trials conducted	0
Publications (please add links to external sources when possible)	Migrant's Health survey Child Care Health Dev. 2017; 1–5. DOI: 10.1111/cch.12538 Oral Health KAP European Journal of Pediatrics https://doi.org/10.1007/s00431-018-3108-z
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Parents survey on Vaccination Confidence in 18 countries
Public involvement	No

eYPAGnet (category 4)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Children and young people's involvement in paediatric clinical trials
Countries involved	UK, Scotland, France, Spain
Number of clinical trials conducted	NA
Publications (please add links to external sources when possible)	Gaillard S , Malik S , Preston J , Nafria B, Dicks P , Touil N , Mardirossian S , Claverol-Torres J , Kassai B Involving Children and Young People in Clinical Research through the forum of a European Young Persons' Advisory Group: Needs & Challenges. Fundam Clin Pharmacol . 2018 Feb 19. doi: 10.1111/fcp.12360. Nafria B, Claverol-Torres J KIDS Barcelona: Young Person's Advisory Group Focused in Clinical Research and Innovation Projects. Chapter of a book. In press Gaillard S , Preston J , Nafria B, Dicks P , Claverol-Torres J Ethics and the Research with Minors Chapter of a book. In press Preston J, Dicks P, Nafria B, Gaillard S. The ethical principles underpinning the participation of young people in the development of paediatric clinical research Chapter of a book. In press
Other activities conducted	Workshop about the 10 years of the Paediatric Regulation.

(e.g. consultation, training, other clinical studies, participation in projects)	<p>March. EMA - London</p> <p>Ethics Working Group of EnprEMA- Consultation about assent templates</p> <p>Presentation of eYPAGnet in the PCDO session- January 2018</p> <p>Clinical Trials Preparedness- Working Group</p> <p>Ethics Working Group of EnprEMA – Participation in a meeting in January of 2018</p> <p>Paediatric Clinical Trials Congress. London. March 2018</p> <p>Conect4Children. Kick of Meeting 23-25 th of May 2018</p> <p>EitHealt project about “Advocacy for young people”. First stage successful. Pending second stage assessment.</p> <p>Anonymization data workshop EMA – 30th of November (London)</p>
Public involvement	<p>Presentation of the network in the ICAN summit- Orlando- July 2017</p> <p>Better medicines for children in London – 16th of October 2017</p> <p>Eye For Pharma in London- 19 th of October 2017</p> <p>TOPRA congress –Brussels -21st of November 2017</p> <p>FarmaIndustria - Madrid- 20 th of September 2017</p> <p>Société Française de Pédiatrie – Lyon – 24-25 May 2018</p>

Severe Paediatric Asthma Collaborative in Europe (SPACE)

Areas of expertise (eg: neonatology, pharmacology, oncology)	Paediatric respiratory
Countries involved	Germany, Italy, The Netherlands, Norway, Portugal, Turkey, UK
Number of clinical trials conducted	N/A
Publications (please add links to external sources when possible)	Liu NM, van Aalderen W, Carlsen KCL, <i>et al.</i> Severe Paediatric Asthma Collaborative in Europe (SPACE): protocol for a European registry. <i>Breathe</i> 2018; 14: 2–8.
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	<ul style="list-style-type: none"> -Literature review to define inclusion/ exclusion criteria for the online registry of paediatric severe asthma across Europe. -Development of the online registry. -Protocol and documents (e.g. consent forms, information sheets) approved by the UK Research Ethical Committee. -Documents translation and local ethical approval pending in other countries.
Public involvement	The registry and all documents were developed with the help of the patient advisory group from European Lung Foundation.

Enpr-EMA overview

The European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) is a network of research networks, investigators and centres with recognised expertise in performing clinical trials in the paediatric population.

Members

Enpr-EMA members perform research in children (from newborns to adolescents) in multiple therapeutic areas, and ranging from pharmacokinetics to pharmacovigilance. A fully searchable database provides easy access to each individual Enpr-EMA network: <http://enprema.ema.europa.eu>

Would you like to join Enpr-EMA?

Networks, centres or investigators interested in becoming members of Enpr-EMA are invited to complete a self-assessment form (available on the European Medicines Agency's website) and send it to:

enprema@ema.europa.eu



Further information

Visit www.ema.europa.eu and click on this banner:



Or contact:

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Enpr-EMA

European Network of
Paediatric Research at the
European Medicines Agency

Mission statement

Enpr-EMA will facilitate studies to increase the availability of medicines authorised for use in the paediatric population.

Aims of the network

Enpr-EMA aims to fulfil its mission by:

- establishing a European paediatric research network of national and European specialist networks, investigators and centres with expertise in performing paediatric clinical trials to foster high-quality, ethical research on the safety and effectiveness of medicines for children;
- efficient inter-network and stakeholder collaboration, to build up the necessary competences at European Union level, and to avoid unnecessary duplication of studies;
- raising awareness among healthcare professionals, parents, carers, children and young people of the need and support for paediatric clinical trials;
- assisting and entering into dialogue with ethics committees on issues relevant to research and clinical trials in children.

Legal background

One of the objectives of the Paediatric Regulation (Regulation (EC) No 1901/2006) is to foster high-quality ethical research on medicinal products to be used in children. This should be achieved through efficient inter-network and stakeholder collaboration.

To meet this objective, the European Medicines Agency established Enpr-EMA, officially launched and presented to stakeholders in March 2011.

Early consultation of Enpr-EMA members is encouraged in the new Commission guideline on paediatric investigation plans (PIPs) to facilitate the development of a PIP.

Recognition criteria

Enpr-EMA's members are required to fulfil a list of criteria in six categories, namely:

- research experience and ability;
- network organisation and processes;
- scientific competencies and ability to provide expert advice;
- quality-management;
- training and educational capacity to build competences;
- public involvement.

Operational structure

The operational centre of Enpr-EMA is the Coordinating Group (CG), which is responsible for the network's long- and short-term strategy.

The European Medicines Agency provides the

secretariat support, and organises and hosts Enpr-EMA meetings. A workshop open to all stakeholders is held at the Agency once a year.

Main tasks of the Coordinating Group

- Facilitate the pharmaceutical industry's access to paediatric clinical-study centres and experts.
- Identify new and emerging networks, and invite them to apply for Enpr-EMA membership.
- Act as a forum for communication.
- Discuss and resolve operational and scientific issues.
- Develop common educational tools for children and parents, and encourage their participation in clinical trials.
- Liaise with the European Medicines Agency's Paediatric Committee (PDCO), which is the scientific committee of the network.