15 May 2017
EMA/452047/2016

2017 annual workshop of the European network of paediatric research at the EMA (Enpr-EMA)

Tuesday 16 May 2017, room 3A

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Workshop programme

Chairpersons: Mark Turner / Irmgard Eichler

Item	Agenda	Topic leader	Action	Time
09:00	Arrival and registration			30’
09:30	Welcome address	Guido Rasi		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** **Interaction of investigators and sponsors**	Mark Turner		
09.55	Feedback from each Working Group on their completed actions, deliverables and identification of follow-on action plans:	Working Group Chair Persons	For discussion	75’
	• WG on GCP Training	Gareth Veal		
	• WG on Ethics	Pirkko Lepola		
	• WG on Young People Advisory Groups	Pamela Dicks		
	• WG on Interaction: network-industry-regulators	Sue Tansey Pirkko Lepola		
	• WG on Antibiotics	Laura Folgori		
11:10	Examples of interaction of investigators – sponsors - regulators:			65’
	• Accelerate and multi-stakeholder interaction oncology	Gilles Vassal		
	• PRINTO	Nicola Ruperto		
	• ECFS	Tim Lee		
	• PENTA	Carlo Giaquinto		
12.15	**Lunch**			60’

Item	Agenda	Topic leader	Action	Time
13.15	**Session 3** **Selected topic discussions**	Mark Turner		
13:15	Update on networks: <u>European networks</u>:		For discussion	60’
	• Spanish Network	Cristina Serens Trasorras		
	• Nordic Network	Kalle Hoppu		
	• Irish Network	Geraldine Boylan		
	• The European Paediatric Clinical Trial Network an IMI2 project	William Treem		
	<u>International networks</u>:			
	• Institute for Advanced Clinical Trials for Children	Ronald Portman		
	• PEDCRIN	Mark Turner		
14:15	EMA framework for collaboration with academia	Isabelle Moulon	For information	10’
14.25	Established European Reference Networks: Potential for interaction with Enpr-EMA networks	Enrique Terol Ruth Ladenstein	For discussion	70’
15.35	Update on implementation of Clinical Trial Regulation: • Update about the EU Clinical Trial Portal • Update EU member state harmonization	Kevin Cunningham Sean Kilbride	For information	25’
16.00	**Coffee break**			20’
16.20	**Session 4** **Interaction and cooperation EU and US on global paediatric research**		For information and discussion	
16.20	Network’s perspective: Collaboration European Cystic Fibrosis Society Clinical Trials Network (ECFS-CTN) with US Cystic Fibrosis Foundation – Therapeutics Development Network (CFF-TDN)	Tim Lee		10’

Item	Agenda	Topic leader	Action	Time
16.30	Regulators' perspective: • Global collaboration with networks FDA and EMA perspective	Susan McCune Irmgard Eichler		20'
	• Feedback from EC/EMA-FDA bilateral on paediatric research	Peter Karolyi		
16.50	Industry perspective	John Watson (EUCOPE) William Treem (EFPIA)		10'
17.00	Young persons' perspective: European Young Persons Groups network	Joana Claverol		15'
17.15	Discussion			40'
17.55	Action points and conclusions	Mark Turner		5'
18.00	**End of workshop**			

List of speakers / chairpersons

Surname	Name	Affiliation
Boylan	Geraldine	Irish Paediatric Clinical Research Network (IPCRN)
Claverol	Joana	Fundació Sant Joan de Déu, Spain
Cunningham	Kevin	European Medicines Agency (EMA), EU
Dicks	Pamela	Chair of WG on YPAG ScotCRN, UK
Eichler	Irmgard	Co-Chair of Enpr-EMA European Medicines Agency (EMA), EU
Fologori	Laura	St George's University London, UK; PENTA-ID
Giaquinto	Carlo	PENTA
Hoppu	Kalle	FINPEDMED, Nordic Network
Karolyi	Peter	Paediatric Medicines Office EMA, EU
Kilbride	Sean	Health Products Regulatory Authority, IE; Clinical Trial Facilitation Group
Ladenstein	Ruth	OKIDS, Austria; Paediatric Cancer ERN
Lepola	Pirkko	Chair of WG on Ethics FINPEDMED, FIN
Lee	Tim	ECFS-CTN
McCune	Susan	Office Pediatric Therapeutics, FDA
Portman	Ronald	Novartis
Ruperto	Nicola	PRINTO
Serens Trasorras	Cristina	Spanish Paediatric Clinical Trials Network (RECLIP)
Terol	Enrique	European Commission, EU
Treem	William	Janssen R&D, USA Representing EFPIA, EU
Turner	Mark	Chair of Enpr-EMA NIHR-CRN:Children, UK
Vassal	Gilles	Innovative Therapies for Children with Cancer (ITCC)
Veal	Gareth	Chair of WG on Training Newcastle CCLG Pharmacology Studies Group, UK
Watson	John	Zogenix International Ltd Representing EUCOPE

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 Wong
Finnish Investigators Network for Pediatric Medicines (FINPedMed)	Kalle Hoppu
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
Medicines for Children Research Network, NL (MCRN-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
Paediatric European Network for the Treatment of AIDS (PENTA)	Carlo Giaquinto
Paediatric Investigation Into Health Products Network (RIPPS)	Behrouz Kassai-Koupai
Pediatric Rheumatology International Trials Organisation (PRINTO)	Nicolino Ruperto
Scottish Medicines for Children Network (scotcrn)	Jurgen Schwarze
United Kingdom Paediatric Vaccines Group (UKPVG)	Paul Heath
PDCO Member	Marek Migdal
PDCO Member	Angeliki Siapkara
Patient representative (EMA PCWP)	Jose Drabwell
Healthcare professionals representative (EMA HCPWP)	Adamos Hadjipanayis
Networks with observer status[1]	
Mother Infant Child Youth Research Network (MICYRN)	Anne Junker
Duke Clinical Research Institute	Brian Smith

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

List of Working Groups:

1.1. Joint working group on public-private partnership

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

1.2. 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.

1.3. Working group on Young patient advisory groups

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

1.4. Working group on GCP training across multispecialty and countries

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

1.5. Working Group on paediatric antibiotic clinical trial design

Working group volunteers: **Mike Sharland**, Laura Folgori, Maria Fernandez Cortizo, Irja Lutsar, Irmgard Eichler, Marco Cavaleri, Emmanuel Roilides, John van den Anker, Joe Standing, Sarah Walker, John Rex, Hasan Jafri, Amanda Paschke

Annual updates from networks 2016-2017

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
Countries involved	US, Canada, Singapore, Israel, United Kingdom
Number of clinical trials conducted	>20
Publications (please add links to external sources when possible)	https://pediatrictrials.org/published-results-presentations-and-articles-of-interest
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Training: >25 total fellows 4 active fellows in training (T32, foundation, and institutional funding) 4 active assistant professors (K-funding) Collaboration: *Eunice Kennedy Shriver* National Institute of Child Health and Human Development US Food and Drug Administration Other US research networks Clinical Studies (non-trials): -meta-analyses -electronic health record data -retrospective analyses
Public involvement	Patient Advocate Review of Study Protocols and Informed Consent Forms

EBMT European Blood and Marrow Transplantation - PDWP Paediatric Diseases Working Party as subgroup of the organisation

Category 1

Areas of expertise (eg: neonatology, pharmacology, oncology)	Pediatric Hematopoietic Stem Cell Transplantation
Countries involved	40 European, 9 non-European countries
Number of clinical trials conducted in 2016:	ALL SCTped 2012 FORUM (“For Omitting Radiation Under Majority Age”) Subsequent allogeneic SCT in paediatric patients: indications, procedures and outcome

	Haematopoietic stem cell transplantation for sickle cell disease: An analysis on behalf of Eurocord, PDWP of EBMT, CIBMTR, USP (Ribeirão Preto) and Ruby Hall Clinic HSCT in children and adolescents with non-hodgkin lymphoma Outcome of children developing grade III-IV acute graft-versus-host-disease after allogeneic haematopoietic stem cell transplantation
Key Publications 2016: (please add links to external sources when possible)	Incidence and severity of crucial late effects after allogeneic HSCT for malignancy under the age of 3 years: TBI is what really matters, Bone Marrow Transplant. 2016 Nov; 51 (11): 1482-1489 Association of CTH variant with sinusoidal obstruction syndrome in children receiving intravenous busulfan and cyclophosphamide before hematopoietic stem cell transplantation, Pharmacogenomics J. 2016 Oct 25. doi: 10.1038 Impact of Conditioning Regimen on Outcomes for Children with Acute Myeloid Leukemia Transplanted in First Complete Remission. an Analysis on Behalf of the Pediatric Disease Working Party of the Ebmt, Biol Blood Marrow Transplant. 2016 Dec 1. pii: S1083-8791 (16) 30522-5 More chronic GVHD and Non-Relapse-Mortality After Peripheral Blood Stem Cell Compared with Bone Marrow in Hematopoietic Transplantation for Paediatric Acute Lymphoblastic Leukemia. A Retrospective Study on behalf of the EBMT Paediatric Diseases Working Party, Bone Marrow Transplant., in press State-of-the-Art Fertility Preservation in Children and Adolescents Undergoing Haematopoietic Stem Cell Transplantation: Report on the Expert Meeting of the Pediatric Diseases Working Party (PDWP) of the European Society for Blood and Marrow Transplantation (EBMT) in Baden, Austria, 29-30 September 2015, Bone Marrow Transplant., in press Fertility preservation practices in paediatric and adolescent cancer patients undergoing HSCT in Europe: a population-based survey, Bone Marrow Transplant., in press Outcome of paediatric patients treated with defibrotide for thrombotic microangiopathy, Bone Marrow Transplant., in press. Hemopoietic stem cell transplantation in thalassemia: a report from the European Society for Blood and Bone Marrow Transplantation Hemoglobinopathy Registry. Baronciani D, Angelucci E, Potschger U, Gaziev J, Yesilipek A, Zecca M, Orofino MG, Giardini C, Al-Ahmari A, Marktel S, de la Fuente J, Ghavamzadeh A,Hussein AA, Targhetta C, Pilo F, Locatelli F, Dini G, Bader P, Peters C. Bone Marrow Transplant. 2016 Apr;51(4):536-41. doi: 10.1038/bmt.2015.293. Epub 2016 Jan 11. PubMed PMID: 26752139. Ethical and Clinical Considerations. Recommendations from a Working Group of the Worldwide Network for Blood and Marrow Transplantation Association. Bitan M, van Walraven SM, Worel N, Ball LM, Styczynski J, Torrabadella M, Witt V, Shaw BE, Seber A, Yabe H, Greinix HT, Peters

	C, Gluckman E, Rocha V, Halter J,Pulsipher MA. Biol Blood Marrow Transplant. 2016 Jan;22(1):96-103. doi:10.1016/j.bbmt.2015.08.017. Epub 2015 Aug 22. Review. PubMed PMID: 26307344. Treosulfan-based conditioning regimens for allogeneic haematopoietic stem cell transplantation in children with non-malignant diseases. Slatter MA, Boztug H, Pötschger U, Sykora KW, Lankester A, Yaniv I, Sedlacek P, Glogova E, Veys P, Gennery AR, Peters C; EBMT Inborn Errors and Paediatric Diseases Working Parties. Bone Marrow Transplant. 2015 Dec;50(12):1536-41. doi: 10.1038/bmt.2015.171. Epub 2015 Aug 10. PubMed PMID: 26259076. Recommendations on hematopoietic stem cell transplantation for inherited bone marrow failure syndromes. Peffault de Latour R, Peters C, Gibson B, Strahm B, Lankester A, de Heredia CD, Longoni D, Fioredda F, Locatelli F, Yaniv I, Wachowiak J, Donadieu J,Lawitschka A, Bierings M, Wlodarski M, Corbacioglu S, Bonanomi S, Samarasinghe S,Leblanc T, Dufour C, Dalle JH; Pediatric Working Party of the European Group for Blood and Marrow Transplantation; Severe Aplastic Anemia Working Party of the European Group for Blood and Marrow Transplantation. Bone Marrow Transplant. 2015 Sep;50(9):1168-72. doi:10.1038/bmt.2015.117. Epub 2015 Jun 8. Review. PubMed PMID: 26052913. Stem cell transplantation in severe congenital neutropenia: an analysis from the European Society for Blood and Marrow Transplantation. Blood. Fioredda F, Iacobelli S, van Biezen A, Gaspar B, Ancliff P, Donadieu J,Aljurf M, Peters C, Calvillo M, Matthes-Martin S, Morreale G, van 't Veer-Tazelaar N, de Wreede L, Al Seraihy A, Yesilipek A, Fischer A, Bierings M,Ozturk G, Smith O, Veys P, Ljungman P, Peffault de Latour R, Sánchez de Toledo Codina J, Or R, Ganser A, Afanasyev B, Wynn R, Kalwak K, Marsh J, Dufour C;Severe Aplastic Anemia the Inborn Error, and the Pediatric Disease Working Parties of the European Society for Blood and Bone Marrow Transplantation (EBMT) and Stem Cell Transplant for Immunodeficiencies in Europe (SCETIDE). 2015 Oct 15;126(16):1885-92;quiz 1970. doi: 10.1182/blood-2015-02-628859. Epub 2015 Jul 16. PubMed PMID:26185129.
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Chair: Peter Bader, Co-Chair: Jean-Hugues Dalle, Secretary: Andre Willasch. The EBMT PDWP held its “10th Scientific Meeting of the EBMT Paediatric Diseases Working Party conducted as joint meeting with the EBMT Inborn Errors Working Party and the 5th Meeting of the EBMT Paediatric Nurses” in May on the island of Rhodes. The local organizer Stelios Graphakos and Peter Bader welcomed 120 participants from 24 countries and Eugenia Trigoso saluted 37 nurses from 8 different countries to Greece. The wide-ranging program included up-to-date contributions on hemoglobinopathies, cellular therapy, GvHD, alternative transplantations, inborn errors, antiviral therapy,

	complications and late effects, like infertility, after SCT. The latter topic had been extensively addressed in a PDWP driven "Expert Workshop on Fertility Preservation in the Context of HSCT" in Baden, Austria, in 2015. The EBMT Annual meeting in Valencia held the 4th Paediatric Day on April 5th 2016 with specific pediatric scientific sessions and topics.
Public involvement	On April 2nd 2016 he "Patient and Family Day" took place during the EBMT annual meeting in Valencia.

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 May 2016 to March 2017: 28 clinical trials were active in the network (all ages)
Publications (please add links to external sources when possible)	Disease-specific clinical trials networks: the example of cystic fibrosis De Boeck, K., Bulteel, V. & Fajac, I. Eur J Pediatr (2016) 175: 817. http://link.springer.com/article/10.1007%2Fs00431-016-2712-z
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	20 completed or ongoing protocol reviews since May 2016 ECFS-CTN Training day for investigators and research coordinators, Basel June 8th 2016 Appointment of a quality manager to improve our quality and performance metrics "Additional Research Capacity" program to support more research personnel at sites and increase the capacity to run trials The Standardisation Committee, in response to discussions with Patient Organisation representatives, has created a new Working Group looking specifically at Patient Reported Outcome Measures (PROMs). The Standardisation Committee produced or revised 2 Standard Operating Procedures related to outcome measures in clinical trials (blood inflammatory markers and sweat test) Co-applicant in 5 H2020 or other European consortiums (ongoing applications)
Public involvement	Continuous close collaboration with national an European patient organizations (protocol review, YPAG initiation, patient friendly activity reports, clinical trial finder, patient referral policies, patient priorities,…)

FINPEDMED- Finnish Investigators Network for Pediatric Medicines.

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
Number of clinical trials conducted	25 (sponsored and academic); until
Publications (please add links to external sources when possible)	http://adc.bmj.com/content/archdischild/early/2016/05/25/archdischild-2015-310001.full.pdf?keytype=ref&ijkey=0ozuUFBDhOiruxr http://www.appliedclinicaltrialsonline.com/print/306311?page=full
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	National level Paediatric Research Nurse training program (4 Credit Units) 2015-2017; completed in 3 University Hospitals: Total of 30 research nurses graduated. Total of 153 Service Requests for new clinical trials and 47 Consultations for PIPs and product / trial development: 2006-2016.
Public involvement	none in 2016

FP-MCRN (Family Paediatricians-Medicines for Children Research Network)

Category 1

Areas of expertise (eg: neonatology, pharmacology, oncology)	Pharmacovigilance (PAS Studies)
Countries involved	Italy
Number of clinical trials conducted	2
Publications (please add links to external sources when possible)	Napoleone E., Lavalle A., Scasserra C., Ricci M. Active Surveillance on the Use of Antibiotics in Children, Particularly in the Age Group from 0 to 2 Years. J Pharmacovigil 2016, 4: 205
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	2 training courses for Family Pediatricians (FP) on : 1) the correct use of antibiotics in early children ; 2) the correct use of Inhaled Steroids (IS) in children . Family Communication: we encouraged closer synergy between the FP and families through better and more accurate information given to families on the correct use of antibiotics and respiratory drugs (in particular of IS) to promote a reduction of the self-

	prescription for illnesses that do not required these drugs (according to international Guidelines)
Public involvement	yes

German Neonatal Network

Category 1

Areas of expertise (eg: neonatology, pharmacology, oncology)	Neonatology
Countries involved	Germany
Number of clinical trials conducted	2
Publications (please add links to external sources when possible)	https://www.ncbi.nlm.nih.gov/pubmed/?term=%22German+Neonatal+Network%22
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Face to face research meetings twice each year. Training of participating researchers for analysis of clinical and biobank data once a year.
Public involvement	Regular involvement in annual meetings of learned societies for Paediatrics and Neonatology in Germany.

International BFM Study Group

Category 1

Areas of expertise (eg: neonatology, pharmacology, oncology)	Pediatric Hamtological Malignancies
Countries involved	1. Europe • 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) • The Netherlands (DCOG) • Turkey • Unit. Kingdom (UKCCLG) • Ukraine 2. Outside Europe • 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)	Annex 1 (available on demand)
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	1. Continuous education through the organization of the Annual Meeting (> 300 participants), several Committees meetings and a Biannual Congress on Childhood Leukemias. 2. Promote the cooperation with countries with limited resources through the organization of international clinical studies.
Public involvement	Interaction with EMA, ASH, SIOPE, ICCCPO and additional national scientific societies, regulatory boards, and disease related international groups.

INFANT: Irish Centre for Fetal and Neonatal Translational Research Cork University Maternity Hospital Wilton, Cork Ireland

Category 1

Areas of expertise (eg: neonatology, pharmacology, oncology)	Neonatal Brain Research - using enhanced real time multi modal physiological monitoring at the cotside. Developing algorithms that can reliably and remotely monitor complex physiological data.

	Biomarker discovery and validation in neonates. Infant and Maternal Nutrition research. CTIMP studies in neonates for hypotension and seizures.
Countries involved	USA, Canada, New Zealand, Australia, UK, The Netherlands, Czech Republic, Hungary, Spain, Sweden, Finland, Germany, Austria, Denmark, France, Belgium.
Number of clinical trials conducted	7
Publications (please add links to external sources when possible)	Annex 1 available on demand
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	INFANT is a participant in (through the Irish Paediatric Clinical Trials Network) in PedCRIN project (Paediatric Clinical Research Infrastructure Network). This was a successful proposal to the EU H2020 Infrastructures call (H2020-INFRADEV-2016-1). PEDCRIN is a three-year project brings together ECRIN and the founding partners of the European Paediatric Clinical Trial Research Infrastructure (EPCT-RI) to develop capacity for the management of multinational paediatric clinical trials. INFANT is a participant in a successful proposal to the Horizon 2020 Research Infrastructures call. EpiCARE - A European Network for rare and complex agreements. Objectives To establish a European neonatal seizures expert group To scale up the neonatal EEG remote monitoring platform (Babylink) for use across Europe To provide guidelines for EEG monitoring in neonates with acute seizures and epilepsies across Europe To develop management guidelines and treatment protocols for neonatal seizures To define and implement standardised outcomes of neonatal seizures To provide a web base educational toolkit for neonatal seizures and epilepsies specifically for health professionals, families and public interest groups To establish a neonatal seizure registry in Europe and promote collaborative research
Public involvement	European Foundation for the Care of Newborn Infants (EFCNI) have been involved in three H2020 consortium applications with INFANT and will provide patient advocacy and patient input and advice to these projects if funded. Mandy Daly Patient advocate and founder of Irish Neonatal Health Alliance which is under the umbrella of EFCNI - European Foundation for the Care of Newborn Infants is an advisor to INFANT.

	Focus groups involving parents of babies that participated in trials with INFANT and who are now being followed up through our newly formed Early Life Lab will be asked to join a panel of interested parents for further advisory groups in INFANT studies.

Maternal Infant Child & Youth Research Network MICYRN-Canada

Category 1

Areas of expertise (eg: neonatology, pharmacology, oncology)	MICYRN captures 70% of high risk maternity beds, all the pediatric tertiary beds, all NICUs, all PICU beds, all specialty clinic practices based at academic teaching hospitals and all pediatric academic ERs in Canada. We can link to community pediatric practices and a national primary care research network, but there is no formal affiliation.
Countries involved	Canada
Number of clinical trials conducted	Currently, there are 1054 registered clinical trials recruiting children in Canada. As noted previously, the majority of these studies are investigator-initiated and increasingly, are behavioural studies that supplement, or do not involve, study of medicines. Virtually all industry-sponsored drug studies are multi-jurisdictional, involving Canada as one of two (with USA) or more (usually EU) countries.
Publications (please add links to external sources when possible)	
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	A principal initiative continues to be work towards sharing data for integration, harmonization and/or analysis across multiple jurisdictions that hold varying legal and ethics policies and procedures. 1.Integrating Biology & the Bedside (i2b2) is a scalable open-source informatics framework to enable secondary usage and sharing of clinical data for discovery research. In a project designed to gain experience with this system, a fully functional i2b2 instance was set for paediatrics diabetes data. It draws clinical data from diabetes clinic databases in several provinces, validates this against provincial administrative health data, and transforms it in an analysis-ready dataset, browsable through the i2b2 interface. A big success was definition of a harmonized data dictionary based on the European SWEET database (http://www.sweet-project.eu/relaunch/index.php/2013-10-25-15-31-11/sweet-dataset). Canadian data is being mapped to this harmonized dictionary which will enable Canadian investigators to directly share data with their European counterparts. 2. Research Advancement through Cohort Cataloguing and Harmonization (ReACH) In partnership with Maelstrom Research, a CIHR-funded registry of metadata from 28 pregnancy and birth cohort studies (1 million records) has been developed to support research.

	Many of these cohort studies are introducing interventions (drug, nutrition, behavioural) and the larger dataset will facilitate trials within the registry, and enable achievement of sufficient numbers for statistical analysis. This project is also a proof of concept for other areas like clinical trials, as cataloguing and harmonization across patient registries will facilitate feasibility assessment and identify participants for new studies; and lay the framework for integration of clinical trial datasets. 3. CanShare is the Canadian arm of the Global Alliance for Genomics and Health, which aims for responsible, secure and effective sharing of genomic and clinical datasets internationally, particularly relevant to work in rare diseases and cancer. MICYRN's Ethics Working Group is involved in development of policy and practical guidance to improve review of data intensive research conducted across multiple countries. MICYRN is also engaged in multiple initiatives to improve the awareness, diagnosis and management of rare diseases. 1. Rare Diseases Model & Mechanisms Network – MICYRN's Core supports this novel initiative that aims to expedite connections between clinicians discovering new genes in patients with rare diseases and model organism scientists who can validate findings, and develop models to study pathogenesis and test therapies. 431 Canadian MO scientists set up to study 5831 genes are in the Network Registry. Partnerships this year were developed with the NIH Undiagnosed Diseases Network, and the Model Organism Screening Center. A number of rare disease patients have directly benefited from precision therapies identified through studies. 2. European Networks of Reference for rare disease – Canada is following closely, the EU strategies to improve the state for rare disease patients. The annual conference of the Canadian Organization for Rare Disorders will focus on Networks; MICYRN's Network Inventory has provided context and connections to leaders of Canadian networks that mirror many of the proposed 24 ERNs. That Accreditation Canada (now Health Standards Organization) has been commissioned to evaluate the ERNs raises the potential to expedite EU-Canadian cross-network collaboration.
Public involvement	Our YPAG is involved in the development of YPAG for several recently funded national chronic disease networks which includes recruitment of new advisors, training, mentoring and oversight.

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	4 ongoing paediatric clinical trials
Publications (please add links to external sources when possible)	1. 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: challenges to run early phase clinical trials for children with leukaemia. Ped Blood Cancer 2017 64: e26351 2. Gota, V, Chinnaswamy, G, Vora, T, Rath, S, Yadav, A, Gurjar, M, Veal, G, Kurkure, P. Pharmacokinetics and pharmacogenetics of 13-cis retinoic acid in Indian high-risk neuroblastoma patients. Cancer Chemother Pharmacol 2016 78: 763-768 3. Veal, GJ, Cole, M, Chinnaswamy, G, Sludden, J, Jamieson, D, Errington, J, Malik, G, Hill, CR, Chamberlain, T, Boddy, AV. Cyclophosphamide pharmacokinetics and pharmacogenetics in children with B-cell non-Hodgkin's lymphoma. Eur J Cancer 2016 55: 56-64 4. Jackson, RK, Irving, JAE, Veal, GJ. Personalisation of dexamethasone therapy in childhood acute lymphoblastic leukaemia. Br J Haem 2016 173: 13-24 5. Walsh, C, Bonner, JJ, Johnson, TN, Neuhoff, S, Ghazaly, EA, Gribben, JG, Boddy, AV, Veal, GJ. Development of a physiologically based pharmacokinetic model of actinomycin D in children with cancer. Br J Clin Pharmacol 2016 81: 989-998 6. Errington, J, Malik, G, Evans, J, Baston, J, Parry, A, Price, L, Johnstone, H, Peters, S, Oram, V, Howe, K, Whiteley, E, Tunnacliffe, J, Veal, GJ. Investigating the experiences of childhood cancer patients and parents participating in optional non-therapeutic clinical research studies in the UK – a qualitative study. Ped Blood Cancer 2016 63: 1193-1197 7. Veal, GJ, Errington, J, Sastry, J, Chisholm, J, Brock, P, Morgenstern, D, Pritchard-Jones, K, Chowdhury, T. Adaptive dosing of anticancer drugs in neonates – facilitating evidence-based dosing regimens. Cancer Chemother Pharmacol 2016 77: 685-692 8. Siebert, N, Eger, C, Seidel, D, Jüttner, M, Zumpe, M, Wegner, D, Kietz, S, Ehlert, K, Veal, GJ, Siegmund, W, Weiss, M, Loibner, H, Ladenstein, R, Lode, HN. Pharmacokinetics and pharmacodynamics of ch14.18/CHO in relapsed/refractory high-risk neuroblastoma patients treated by long term infusion in combination with IL-2. mAbs 2016 8:

	604-616
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: 1. 108th Annual Meeting of the AACR, Washington, USA (April, 2017) 2. Annual British Pharmacology Society Meeting, London (December, 2016) 3. 2016 National Cancer Research Institute (NCRI) Conference, Liverpool, UK (November, 2016) 4. Children with Cancer UK Childhood Cancer 2016 Meeting, London (September, 2016) 5. 17th Advances in Neuroblastoma Research Meeting, Cairns, Australia (June, 2016) Training provided to research nurses at paediatric oncology clinical centres relating to study management, sample handling, data analysis and GCP issues. Training Day held in May, 2016, attended by 18 nurses from 9 national clinical centres.
Public involvement	Worked with the patient advocacy group PORT in relation to the information sheets provided as part of a new clinical trial and as a collaborator on a new clinical registry relating to clinical pharmacology data in neonates and other hard to treat patient groups.

NorPedMed

Category 1

Areas of expertise (eg: neonatology, pharmacology, oncology)	NorPedMed is a multi-specialty research network, i.e. covers all paediatric sub-specialities.
Countries involved	Norway
Number of clinical trials conducted	3 of the 24 are completed and 21 are still ongoing. In addition to these studies the Paediatric Oncologists in NorPedMed are involved in paediatric oncology protocols, which contain research questions. There are about 20 protocols. We have applied to expand a clinical trial involving botox treatment in Cerebral Palsey through the PedCRIN network.
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:** Development and evaluation of a test program for Y-site compatibility testing of total parenteral nutrition and intravenous drugs. Staven V, Wang S, Grønlie I, Tho I. Nutr J. 2016 Mar 22;15:29 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 **Publications by NorPedMed representatives:** Annex available on demand
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	NorPedMed was responsible for planning and chairing the Nordic Pediatric Research Network Workshop at the NRI conference 2016. Samantha Scarlett (NorPedMed) was a speaker in the main session "The potential of Nordic research projects". NorPedMed (as a part of MCNN) and the Norwegian Paediatric Association invited Global Research in Paediatrics (GRiP) to hold their roadshow in Norway, in Oslo January 19th 2016. Presentations by NorPedMed representatives: Magnus Aassved Hjorth, NOPHO congress 2016, The phosphate PPL-3 is expressed in B-ALL cells and involved in adhesion and migration. For which he received the NOPHO-price award 2016. Heidi Glosli presented 'NorPedMed – a model equipped for the future' at a meeting at the Norwegian Research Council 10th of March 2016. Several of our representatives has given talks about paediatric clinical trials for medical students, both at ground level and in the medical student research programs, as well as for phd-students. **Participation in projects:** NordicPedMed: a Nordic development project funded by NordicTrial Alliance. The ultimate aim of NordicPedMed is to develop a Nordic network of investigators, centres and national networks with recognized expertise in performing clinical studies on children and increase cooperation between investigators both on a Nordic and European level. NordicPedMed is now established. NorPedMed is associated with NorCRIN, Camilla Tøndel is the vice chair of NorCRIN and is responsible for paediatrics within NorCRIN. NorPedMed is a part of PedCrin, which brings ECRIN and the European Paediatric Clinical Trial Research Infrastructure (EPCTRI) together. ECRIN received funding for creation of PedCRIN in September 2016. NorPedMed has joined the Collaborative Network for European Clinical Trials for Children, CONECT4Children.
Public involvement	Heidi Glosli has been interviewed by "Alt om din helse" regarding paediatric clinical studies: http://www.altomdinhelse.no/kreft/forskning-ticfg/-kliniske-studier-er-nokkelen-til-medisinsk-utvikling Camilla Tøndel was featured by the same magazine, with her research on Fabry: http://www.altomdinhelse.no/sjeldne/ny-forskning-paa-

	fabry-sykdom Camilla Tøndel: Trials on influenza vaccination in children, in Bergens Tidene (a regional newspaper): http://www.bt.no/nyheter/lokalt/Influensavaksine-virker-bedre-pa-barn-enn-voksne-322296b.html?spid_rel=2 Camilla Tøndel participated in a panel debate about paediatric clinical studies in Norway, the debate was organised by the students at The Medical Student Research Programme at The Faculty of Medicine and Dentistry: https://eureka.b.uib.no/2016/06/22/arets-forskningdebatt/

OKIDS

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	95 supported studies 34 conducted studies
Publications (please add links to external sources when possible)	Monatsschrift Kinderheilkunde 2013 · 161:316–324 (update 2017) DOI 10.1007/s00112-012-2792-4 Online publiziert: 24. März 2013 Österreichisches Forschungsnetzwerk für Arzneimittelforschung (OKIDS) Rahmenbedingungen, Ziele und einen europäischer Rundumblick
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	64 feasibilities / enquiries for trials GCP trainings
Public involvement	Collaboration with EUPATI

PEDMED-NL (Previously MCRN 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
Number of clinical trials conducted	3 (EU FP7 funded projects)
Publications (please add links to external sources when possible)	-
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Feasibilities for companies/CRO's Contact to connect companies with KoLs.
Public involvement	-

Paediatric Rheumatology International Trials Organization (PRINTO)

Category 1

Areas of expertise (eg: neonatology, pharmacology, oncology)	Pediatric Rheumatology and Autoinflammatory Diseases
Countries involved	About 80 countries worldwide (Albania, Algeria, Argentina, Armenia, Australia, Austria, Bahrain, Bangladesh, Belgium, Bolivia Plurinational State of, Bosnia and Herzegovina, Brazil, Bulgaria, Chile, China, Colombia, Costa Rica, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Dominican Republic, Ecuador, Egypt, El Salvador, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, India, Indonesia, Iran Islamic Republic of, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kenya, Korea Republic of, Kuwait, Latvia, Lebanon, Libya, Lithuania, Luxembourg, Malaysia, Mexico, Moldova Republic of, Morocco, Netherlands, New Zealand, Norway, Oman, Palestinian Territory Occupied, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Taiwan Province of China, Thailand, Tunisia, Turkey, Ukraine, United Arab Emirates, United Kingdom,Venezuela Bolivarian Republic of.)
Number of clinical trials conducted	6 on-going projects; for more details the information can be retrieved at PRINTO website under the section "on-going projects"

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)	PRINTO is working with pharmaceutical companies as advisor for trials planning, centre selection, data collection, data analysis and interpretation, and data reporting. In the last few years there has been an implementation of several clinical trials in JIA with non-steroidal-anti-inflammatory-drugs and biologic agents. For more information you can see the PRINTO website's page "on-going projects, liaisons with pharmaceutical companies".
Public involvement	PRINTO collaborates with Italian Ministry of Health, the Italian Agency for Drugs (AIFA), European Commission.

RIPPS – Réseau d'Investigation Pédiatrique des Produits de Santé

Category 1

Areas of expertise (eg: neonatology, pharmacology, oncology)	Pharmacology Existing Sub-networks Mental disabilities, Autism (RIPPS Defiscience), Epilepsy (RIPPS Perene), Neuromuscular Disorders (RIPPS Neuromus) Sub-networks in construction Metabolic diseases, Pediatric Ambulatory Medicine, pediatric Emergency Medicine Rare diseases Clinical coordination and project management
Number of clinical trials conducted	43
Publications (please add links to external sources when possible)	- Nguyen KA, Claris O, Kassai B. Unlicensed and off-label drug use in a neonatal unit in France. Acta Paediatr. 2011 Apr;100(4):615-7. 10.1111/j.1651-2227.2010.02103.x - De Boeck K, Bulteel V, Tiddens H, Wagner T, Fajac I, Conway S, Dufour F, Smyth AR, Lee T, Sermet I, Kassai B, Elborn S; ECFS-CTN network partners. Guideline on the design and conduct of cystic fibrosis clinical trials: the European Cystic Fibrosis Society-Clinical Trials Network (ECFS-CTN). J Cyst Fibros. 2011 Jun;10 Suppl 2:S67-74. 10.1016/S1569-1993(11)60010-6 - Martine Wallon, François Kieffer, Christine Binquet, Philippe Thulliez, Patricia Garcia-Méric, Pascal Dureau, Jacqueline Franck, François Peyron, Alain Bonnin, Isabelle Villena, Claire Bonithon-Kopp, Jean-Bernard Gouyon, Sandrine Masson, Alexandrin Félin, Catherine Cornu. Toxoplasmose congénitale : comparaison randomisée de stratégies de prévention des rétinochoroïdites. Thérapie Volume 66, Issue 6, November–December 2011, Pages 473–480. 10.2515/therapie/2011070 - Nguyen KA, Zmeter G, Claris O, Kassai B. Epidemiology of invasive

Candida infection in a neonatal intensive care unit in France. Acta Paediatr. 2012 Mar;101(3). 10.1111/j.1651-2227.2011.02514.x
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- Lajoinie A, Henin E, Nguyen KA, Malik S, Mimouni Y, Sapori JM, Bréant V, Cochat P, Kassai B. Oral drug dosage forms administered to hospitalized children: Analysis of 117,665 oral administrations in a French paediatric hospital over a 1-year period. Int J Pharm. 2016 Mar 16; 500(1-2):336-44. 10.1016/j.ijpharm.2016.01.048
- Walch AC, Henin E, Berthiller J, Dode X, Abel B, Kassai B, Lajoinie A; EREMI Group. Oral dosage form administration practice in children under 6 years of age: A survey study of paediatric nurses. Int J Pharm. 2016 Sep 25; 511(2):855-63. 10.1016/j.ijpharm.2016.07.076
- Mietton C, Schaeffer L, Streichenberger N, Cunin V, Kassai B, Poirot I. Physiological anatomy of botulinum toxin effect on the spastic muscle of children with cerebral palsy. Ann Phys Rehabil Med. 2016 Sep; 59S:e6. 10.1016/j.rehab.2016.07.015
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	- Salma Malik, Thomas Cotte, Nicolas Jomard, Marcel Fodor, Martin Gillet, Behrouz Kassaï. Impliquer les enfants et les jeunes dans la recherche clinique en France : le pari de KIDS-France *(accepted « Les Archives de Pédiatrie » Oct 2016).* - Salma Malik, Segolene Gaillard, Nathalie Touil, Behrouz Kassaï, Involving Children and Adolescent in Clinical Research: Necessities and Challenges (*Submitted to the journal of Fundamental & Clinical Pharmacology, Nov 2016*). - Janiaud P, Cornu C, Lajoinie A, Djemli A, Cucherat M, Kassai B. Is the perceived placebo effect comparable between adults and children? A meta-regression analysis. Pediatr Res. 2017 Jan; 81(1-1):11-17.
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	RIPPS DSMB: Data monitoring committee management, ECFS CTN members. EUDIPHARM, GCP, CLIC PharmaTrain/ECRIN: training course Clinical research support, feasibility studies, PIP assistance Data center ECRIN Enpr-EMA Working groups: GCP, YPAG, Trial preparedness
Public involvement	Patients (RIPPS EUPATI): EUPATI France Project (European Patients Academy on therapeutic Innovations) Children and young patients (RIPPS KIDS Fr): ICAN Kids France; eYPAGnet co-founder

TEDDY Network - European Network of Excellence for Paediatric Clinical Research

Category 1

Areas of expertise (e.g.: neonatology, haematology, pain, neurology, infectivology)	Multispecialty network
Countries involved	Europe: Cyprus, Czech Republic, France, Germany, Greece, Italy, The Netherlands, Poland, Romania, Spain, Sweden, UK. Outside Europe: Albania, China, Egypt, Israel, Lebanon, Tunisia, Ukraine.
Number of clinical trials conducted	9 (4 completed and 5 ongoing)
Publications (please add links to external sources when possible)	Giannuzzi V, Devlieger H, Margari L, Odlind VL, Ragab L, Bellettato CM, D'Avanzo F, Lampe C, Cassis L, Cortès-Saladelafont E, Cazorla ÁG, Barić I, Cvitanović-Šojat L, Fumić K, Dali CI, Bartoloni F, Bonifazi F, Scarpa M, Ceci A. The ethical framework for performing research with rare inherited neurometabolic disease patients. Eur J Pediatr. 2017 Mar;176(3):395-405. doi: 10.1007/s00431-017-2852-9. Abstract available at:

	https://www.ncbi.nlm.nih.gov/pubmed/28093642 Ceci A, Giannuzzi V, Bonifazi D, Felisi M, Bonifazi F and Ruggieri L Clinical Trials in Paediatrics — Regulatory and Methodological Aspects. Drug Discovery and Development - From Molecules to Medicine, Prof. Omboon Vallisuta (Ed.), ISBN: 978-953-51-2128-2, InTech, DOI: 10.5772/60611. Available at: http://www.intechopen.com/books/drug-discovery-and-development-from-molecules-to-medicine/clinical-trials-in-paediatrics-regulatory-and-methodological-aspects Giannuzzi V, Altavilla A, Ruggieri L, Ceci A Clinical Trial Application in Europe: What Will Change with the New Regulation? Sci Eng Ethics. 2015 Jun 3. [Epub ahead of print] Abstract available at: https://www.ncbi.nlm.nih.gov/pubmed/26037896
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Participation in: - Survey for Enpr-EMA networks regarding Young Persons Groups (April 2016) - Public consultation on "Summary of Clinical Trial Results for Laypersons" (August 2016) - Public consultation on the revision of "Ethical Considerations for Clinical Trials on Medicinal products conducted with Minors" (August 2016) - Survey of Young Persons Groups (YPAG) in Europe (January 2017) - Public consultation to gather stakeholders' experiences of the EU Paediatric Regulation (February 2017) Launch of the TEDDY survey to map experience and expertise of European clinical in paediatric clinical research (October 2016) Establishment of a TEDDY working group to develop a consensus statement on Off-Label Use Practices (GOLUP) in paediatric settings (June 2016) Participation in the PedCRIN (Paediatric Clinical Research Infrastructure Network) project (INFRADEV-3 call), launched on 1 January 2017. Organisation of the Scientific Meeting and General Assembly entitled “The paediatric theme in the forthcoming clinical research scenario“, held in Rome on December 19th, 2016 Participation as founder partner in INCIPIT - the Italian Network for Paediatric Clinical Trials coordinated by Ospedale Pediatrico Bambino Gesù of Rome (Italy).

Public involvement	Patients and families are involved in the preparation of information packages for patients and parents (videos, leaflets, etc.) also through the organisation of focus groups. TEDDY is establishing an YPAG (Young Persons Advisory Group) in Bari at the University paediatric hospital "Giovanni XXIII" to be involved in the design of paediatric studies and in the preparation of consent/assent forms.

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 intesive care and paediatric surgery
Countries involved	1 (SPAIN)
Number of clinical trials conducted	Number of completed trials: 22 Number of ongoing trials: 13
Publications (please add links to external sources when possible)	**Available on request:** Number of publications (YEAR 2016): 199 Number of publications (YEAR 2017): 57
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Training courses received over the last year: 4 Sponsorship of courses organized in the last year by members of the research network: 6 Participation in other research studies: 9 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)

Futurenest Clinical Research

Category 3

Areas of expertise (eg: neonatology, pharmacology, oncology)	General Paediatrics - Outpatient care : adolescent medicine, allergology vaccines, otorhinolaringology, gastroenterology, pulmonology, dermatology, infectious diseases, neurology, nutrition, psychiatry, ophthalmology, nephrology, urology, paediatric rehabilitation, child pain management, paediatric clinical pharmacology, psychology
Countries involved	Hungary
Number of clinical trials conducted	3
Publications (please add links to external sources when possible)	https://www.ncbi.nlm.nih.gov/pubmed/26762528
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Participation in Hungarian General Paediatrician Network – HunPedNet organisation, Collaboration with MCRN-Hungary
Public involvement	No

Juvenile Scleroderma Working Group of the Pediatric Rheumatology European Society (JSWG of PRES)

Category 3

Areas of expertise (eg: neonatology, pharmacology, oncology)	Juvenile scleroderma
Countries involved	Multination – European, North and South American and Near East as Asia
Number of clinical trials conducted	One Observational prospective cohort triala
Publications (please add links to external sources when possible)	Two major submitted papers: - CHARACTERISTICS AT INITIAL ASSESSMENT OF THE FIRST 80 PATIENTS INCLUDED IN THE JUVENILE SYSTEMIC SCLEROSIS INCEPTION COHORT. WWW.JUVENILE-SCLERODERMA.COM - Development of Minimum Standards of Care for Juvenile Localized Scleroderma
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Advice for phase II /III studies in juvenile systemic scleroderma

Public involvement	Cooperation with the Scleroderma Foundation

MCRN- Hungary

Category 3

Areas of expertise (e.g.: neonatology, pharmacology, oncology)	Allergology Cardiology Central Nervous System Diabetes Gastroenterology Infectology Oncology Orthopedia Pulmonology Rare diseases
Countries involved	Hungary
Number of clinical trials conducted	N.A.
Publications (please add links to external sources when possible)	Publications Dr Renczes Gábor: [A gyermekgyógyászati klinikai vizsgálatok és a gyermekgyógyászati vizsgálói hálózat hazai kialakítása] IME XII (8): 51-53, 2013 /Pediatric Clinical Research and the creation of a national pediatric clinical research network/. [In Hungarian] Dr Altmann Anna, Dr Skorán Ottó, Dr Renczes Gábor: [Gyermekek a klinikai vizsgálatokban], Gyermekgyógyászati Továbbképző Szemle, November 2014 /Children in Clinical Trials. [In Hungarian]
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Succesful National Grant Application: Project title: “Creation of a National Clinical Research Site Register and Preparation of Research sites for Participation in International Clinical Trials (ED-15)” (2015-ongoing) Organization of International Pediatric Drug Development Conferences’: 28-29 October 2014, Budapest, 27-28 April 2016; Participation in H2020 founded PEDCRIN project via HECRIN; Registered as partner in IMI2 call topic 4.
Public involvement	

Pediatric Clinical Investigation Center

Category 3

Areas of expertise (eg: neonatology, pharmacology, oncology)	all pediatric subspecialities can be covered
Countries involved	*France, Latvia, Sweden, England, Brazik*
Number of clinical trials conducted	25 We received the full accreditation from the AAHRPP (Association for the Accreditation of Human Research Protection Program)
Publications (please add links to external sources when possible)	2016 see document in copy
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Participation in multiple expert groups on a national and international level, regular meetings with Belgian Regulatory authorities (AFMPS). Our center has the expertise in paediatric gastroeneterology and hepatology and also metabolic disease (orphan disease) to provide competent consultation to regulatory authorities if required
Public involvement	Multiple contact are established between our paediatric clinical investigation center and patients organization in differend fields such as informations on drug therapy, new device available, development of new studies

RECLIP, Spanish Paediatric Clinical Trials Network

Category 3

Areas of expertise (eg: neonatology, pharmacology, oncology)	Cardiology, Endocrinology, Gastroenterology and nutrition, Infectious diseases and vaccines, , Intensive care, Neonatology, Neurology, Onco- hematology, Pneumology, Rheumatology, Metabolic diseases, Allergology, Psychiatry, Dermatology, etc. All conditions covered by specialties and subspecialties.
Countries involved	Spain
Number of clinical trials conducted	2, currently ongoing: *Effects of Different ARA Formulations of Infant Formula on Fatty Acid Status, Immune Markers and Infection Rates in Infants.* *A Phase 1/2, randomized, observer-blind, controlled, multi-center, dose-escalation study to evaluate safety, reactogenicity and immunogenicity of GSK Biologicals' respiratory syncytial virus (RSV)*

Publications (please add links to external sources when possible)	No publications have been made yet as a Network.
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	1. March2017. 10th of Technological Platforms of Biomedical Research. Cristina Calvo, member of RECLIP. http://www.medicamentos-innovadores.org/sites/default/files/medinnovadores/Espa%C3%B1ol/Eventos/2017/X%20Conferencia%20Anual/Programa%20Conferencia%20Marzo%202017_v10%20C.pdf 2. April2017. II Neumoforo. Federico Martinón, Coordinator of RECLIP. https://neumoexpertosdotorg.files.wordpress.com/2016/09/prg_ii_neumoforo_.pdf 3. April 2017. Research on Vaccine for nurses. Federico Martinón, Coordinator of RECLIP. http://www.regalip.org/upload/File/7-jornada-interactiva-sobre-vacunas-para-enfermeria.pdf
Public involvement	

RITIP (Traslational Research Network in Pediatric Infectious Diseases)

Category 3

Areas of expertise (eg: neonatology, pharmacology, oncology)	Infectious Diseases and Vaccines
Countries involved	Spain
Number of clinical trials conducted	1 RSV PED-002
Publications (please add links to external sources when possible)	García-García ML, Calvo C, Rey C, Díaz B, Molinero MD, Pozo F, Casas I. Human metapnuemovirus infections in hospitalized children and comparison with other respiratory viruses. 2005-2014 prospective study. PLoS One. 2017 Mar 16;12(3):e0173504. doi: 10.1371/journal.pone.0173504. eCollection 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5354294/ Martín Del Valle F, Calvo C, Martinez-Rienda I, Cilla A, Romero MP, Menasalvas AI, Reis-Iglesias L, Roda D, Pena MJ, Rabella N, Portugués de la Red MD, Megías G, Moreno-Docón A, Otero A, Cabrerizo M; Grupo de Estudio de las infecciones por enterovirus y parechovirus en niños. Epidemiological and clinical characteristics of infants admitted to hospital due to human parechovirus infections: A prospective study in Spain. An Pediatr (Barc). 2017 Mar 29. pii: S1695-4033(17)30054-1. doi: 10.1016/j.anpedi.2017.02.009.

	https://www.ncbi.nlm.nih.gov/pubmed/28365283 Calvo C, de Ceano-Vivas M. Fever of unknown origin in infants less than 3 months of age. What's new? An Pediatr (Barc). 2017 Mar 30. pii: S1695-4033(17)30080-2. doi: 10.1016/j.anpedi.2017.02.013. https://www.ncbi.nlm.nih.gov/pubmed/28366697 García-García ML, Calvo C, Moreira A, Cañas JA, Pozo F, Sastre B, Quevedo S, Casas I, del Pozo V. Thymic Stromal Lymphopoietin, IL-33 and periostin in hospitalized infants with viral bronchiolitis. Medicine (In press). "New diagnoses of HIV infection in the Spanish Paediatric HIV Cohort (CoRISpe) from 2004 to 2013" Santiago Jiménez de Ory, María Isabel González-Tomé ,Claudia Fortuny, Maria Jose Mellado, Pere Soler-Palacin, Matilde Bustillo, José Tomas Ramos, Maria Angeles Muñoz-Fernández, Maria Luisa Navarro,Working groups of CoRISpe . Medicine 2017. (In press).
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	Education: VI DAY OF PEDIATRIC TROPICALS DISEASES. "Emerging and epidemic diseases" 30th January 2017. Hospital La Paz. Madrid. Spain. INTRODUCTION TO INTERNATIONAL HEALTH, WITH SPECIALIZATION IN: INTERNATIONAL COOPERATION, CLINICAL APPROACH TO TROPICAL PATHOLOGY, PEDIATRICS IN INTERNATIONAL HEALTH AND LABORATORY IN INTERNATIONAL HEALTH (www.ritip.org) JOURNEY OF INFECTIONS IN IMUNOCOMPROMISED CHILDREN. 3th April 2017. H. Clínico San Carlos. Madrid. Spain 7th INTERACTIVE SESION IN VACCINES FOR NURSES. 25th April 2017. Santiago de Compostela. Spain. 8th INTERACTIVE INFECTIOUS DISEASE WORKSHOP. 23-24th November 2017. Santiago de Compostela. Spain.
Public involvement	

SwissPedNet

Category 3

Areas of expertise (eg: neonatology, pharmacology, oncology)	Conduct clinical trials devoted to children ranging from new-borns to adolescents, in all paediatric disciplines.

Countries involved	Switzerland
Number of clinical trials conducted	SwissPedNet is the Swiss Research Network of Clinical Paediatric Hubs. SwissPedNet provides research infrastructure for their members and does not count the clinical trials conducted in the nine paediatric hubs.
Publications (please add links to external sources when possible)	
Other activities conducted (e.g. consultation, training, other clinical studies, participation in projects)	SwissPedNet is recognised as research infrastructure of national relevance and receives federal funding in the funding period 2017 to 2020 to establish and maintain the clinical paediatric hubs. SwissPedNet is part of H2020 funded PedCRIN project. SwissPedNet Clinical Research Session: a platform for young researchers to present and discuss their work with senior and highly experienced paediatricians and researchers. SwissPedNet Travel Award: call for travel awards up to CHF 1000.- to young researchers who travel for short research trainings or research stays.
Public involvement	SwissPedNet follows the activities of EUPATI CH and thinks about a membership there. Beside this public involvement is handled project or study based.

2018 Enpr-EMA workshop will take place on 7 June 2018