19 May 2015
EMA/150699/2015
Product Development Scientific Support Department

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

Thursday 28 May 2015, Room 3A

Chairpersons: Mark Turner / Irmgard Eichler

Item	Agenda	Topic leader	Action	Time
10:00	Arrival and registration			30’
10:30	Welcome address	Jordi Llinares		5’
10:35	**Session 1** Update on the Enpr-EMA activities	Mark Turner Irmgard Eichler		
10:35	Report from the coordinating group (CG) Update on Enpr-EMA activities, achievements and challenges	Mark Turner	For information	20’
10.55	**Session 2** Update on the Enpr-EMA Working Groups	Mark Turner		
10.55	Feedback from each Working Group on their completed actions, deliverables and identification of follow-on action plans	Working Group Chair Persons	For discussion	125’
13.00	**Lunch**			60’
14.00	**Session 3** Selected topic discussions	Mark Turner		
14:00	Update on networks: <u>International networks</u>: • Global Paediatric Clinical Trial Network;	Mark Turner William Treem	For discussion	50’
	• Canadian network;	Anne Junker		
	• Expansion of the Japan Network.	Hidefumi Nakamura		

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Item	Agenda	Topic leader	Action	Time
	<u>European networks</u>: • European networks;	William Treem/Mark Turner		
	• Nordic network.	Kalle Hoppu		
14:50	Various models of Network functioning (3 examples):		For discussion	30’
	• Finnish Investigators Network for Pediatric Medicines FINPEDMED (National Network)	Pirkko Lepola		
	• Paediatric European Network for the Treatment of AIDS and Infectious Diseases PENTA-ID (Specialty Network)	Mike Sharland		
	• CLINICOBRU	Florence Bosco		
15:20	Update from Industry Representatives: • Orphan Medical Products in paediatrics: current situation on access to treatments	Genevieve Michaux	For discussion	40’
	• How to develop sustainable pediatric networks beyond initial IMI2 or other national government agency support	William Treem		
16:00	Neonatology initiatives	Mark Turner	For discussion	20’
16:20	**Coffee break**			15’
16:35	Initiative form the European Clinical Trial Research Infrastructure for the European Strategy Forum for Research Infrastructure (ESFRI)	Mark Turner	For information	15’
16:50	Involvement of children in research: • Feedback from the International Children’s Advisory Network (ICAN) Research after 1 year establishment;	Charles Thompson	For discussion	55’
	• GRiP online guidance platform on setting up and maintaining Young Person Advisory Groups (YPAGs);	Anne Junker		
	• GRiP initiative to develop practical tools to assist in Ethics review of pediatric clinical trials;	Anne Junker		
	• Establishment of an YPAG within the EMA Patients and Consumers Working Party.	Irmgard Eichler / Nathalie Bere		

Item	Agenda	Topic leader	Action	Time
17.45	Action points and conclusions	Mark Turner	For discussion	15’
18.00	**End of workshop**			

Close session:

Item	Agenda	Topic leader	Action	Time
18.00	**Session 4** Network Business Meeting	Mark Turner		
18:00	Business meeting for the European Strategy Forum for Research Infrastructure (ESFRI): Learning and sharing good practices between Network	Mark Turner	For discussion	60’

1. List of speakers

Surname	Name	Affiliation
Bere	Nathalie	European Medicines Agency, EU
Bosco	Florence	CLINICOBRU, BE
Dicks	Pamela	Chair of WG on EU multi-languages of YPAG ScotCRN, UK
Eichler	Irmgard	Co-Chair of Enpr-EMA European Medicines Agency, EU
Faust	Saul	Chair of WG on interactions network-industry-regulators when implementation/conduct of clinical trials agreed in PIPs is no longer possible NIHR Wellcome Trust Clinical Research Facility, UK
Giaquinto	Carlo	PENTA-ID, IT
Hoppu	Kalle	FINPEDMED, FIN
Junker	Anne	Maternal Infant Child & Youth Research Network, CA
Lepola	Pirkko	Chair of WG on Ethics FINPEDMED, FIN
Llinares Garcia	Jordi	European Medicines Agency, EU
Michaux	Geneviève	Hunton & Williams, BE Representing EUCOPE, EU
Macfarlane	Susan	Chair of WG on GCP training across multispecialty and countries ScotCRN, UK
Nakamura	Hidefumi	Japanese Children Trials Network, JP
Sharland	Mike	Chair of WG on priority setting St George's University London, UK
Tansey	Susan	Chair of WG on public-private partnership Premier Research Group Ltd, UK
Thompson	Charles	Pfizer, USA
Treem	William	Janssen R&D, USA Representing EFPIA, EU
Turner	Mark	Chair of Enpr-EMA chair of WG on neonatology, and WG on network funding, sustainability and FP7 Projects NIHR CRN:Children, UK

2. List of Working Groups:

2.1. Joint Working Group on priority setting

Working group volunteers: Mike Sharland, Edwin Spaans, Gilles Vassal, Ralf Herold, Andrea Biondi, Klaus Hartmann, Jenny Preston, Gareth Veal, Pamela Dicks.

2.2. Joint working group on public-private partnership

Working group volunteers: Susan Tansey, Pamela Dicks, Matthew McClure, Ron Portman, Klaus Hartmann, Andrew Pearson, Christina Peters, Richard Trompeter, Nicola Ruperto, Charles Thompson (Pfizer), Martine Dehlinger-Kremer, Ralf Herold, Jenny Preston, Lynda Wight, Pirkko Lepola, Stefanie Breitenstein.

2.3. Working group on Ethics

Working group volunteers: **Pirkko Lepola**, Allison Needham, Jo Mendum, Richard Trompeter, Alan Boddy, Peter Salabank, David Neubauer, Ralf Herold, Saskia de Wildt, Adriana Ceci; Rafał Świerzewski, Susanne Lau.

2.4. Working group on interactions network-industry-regulators when implementation / conduct of clinical trials agreed in PIPs is no longer possible

Working group volunteers: **Saul Faust**, Ron Portman, Angeliki Siapkara, Ivan Foeldvari, Edwin Spaans, Tim Lee, Christina Peters, Andrew Pearson, Andrea Biondi, Stefanie Breitenstein, Ralf Herold.

2.5. Working group on Neonatology

Working group volunteers: **Mark Turner**, Ralph Bax, Wolfgang Goepel, Hector Rojas, Heike Rabe, Irja Lutsar, Evelyne Jacqz-Aigrain, Thorsten Olski, Stefanie Breitenstein.

2.6. Joint working group on network funding, sustainability and FP7 Projects

Working group volunteers: **Mark Turner**, Kalle Hoppu, Tim Lee, Stephen Greene, Carlo Giaquinto, Nicola Ruperto, Saul Faust, Saskia de Wildt, David Coghill, Gabriella Hajdu, Evelyne Jacqz-Aigrain, Ralph Bax, Adriana Ceci, Stephanie Laeer, Heike Rabe, Gilles Vassal, Geraldine Boylan, Ronit Pressler

2.7. Working group to address issues with EU multi-languages of Young patient advisory groups

Working group volunteers: **Pamela Dicks**, Anne Junker, Winnie Chan, Charles Thompson, Jenny Preston, Rafał Świerzewski, Adamos Hadjipanayis

2.8. Working group on GCP training across multispecialty and countries

Working group volunteers: **Susan Macfarlane**, Pirkko Lepola, Hector Rojas, Paolo Rossi, Montserrat Alvaro Lozano

3. Briefing paper: Important news from individual Enpr-EMA networks since the 2014 Enpr-EMA workshop:

3.1. German Neonatal Network GNN, Enpr-EMA category 1 network

Between June 2014 and Feb. 2015 the GNN published several papers which are relevant with regard to the treatment of preterm infants with a birth weight below 1500 grams.

Two manuscripts report on a new method of surfactant administration to spontaneously breathing infants. One is a large matched pairs analysis from our network involving more than 1100 infants who were treated with the new method, published in Acta Paediatrica (2015 104:241-6), the other is a randomized controlled trial involving preterm infants with a gestational age between 23 and 26 weeks which is right now in press at JAMA Pediatrics.

In August 2014, we published observational data on the effect of prophylactic use of probiotics in the GNN Network (J Pediatr 2014; 165:285-9). This issue is important because we observed a significant reduction of necrotizing enterocolitis which is treated with surgery in neonatal intensive care units using prophylactic probiotics. To prevent a disease which must be treated with surgery by a simple nutritional supplement is great.

A third focus of our network efforts was a pharmacogenetic study involving genotyping data of more than 7000 preterm infants. We analysed a very rare mutation of the mitochondrial genome, which has been reported to be associated with permanent hearing loss in children and adults who are treated with aminoglycoside antibiotics. Because aminoglycoside treatment is very common in preterm infants, we analysed our database and were able to confirm the previously reported association, although only 3 out of ten babies who carried the mutation failed hearing screening (BMC Pediatr 2014; 14:210).

3.2. Maternal Infant Child & Youth Research Network (MICYRN-Canada), Enpr-EMA category 1 network

A. Clinical Trials

1. Research Infrastructure:

The Canadian federal government does not yet require pediatric clinical trials be conducted, and yet there is great commitment within the child health community in the country to see this happen. 2014 began with a national meeting we organized with the Canadian Institutes of Health Research (CIHR) Institute of Genetics and the Drug Safety and Effectiveness Network (DSEN) on Innovative Trials in Small Populations which brought together ~80 people including our research institute directors, investigators and research manager/coordinators, and statistician/methodologists. Dr. Stuart MacLeod who had chaired the Canadian Council of Academies (CCA) review panel on the State of Pharmaceuticals for Children in Canada, urged development of a national research infrastructure business plan that would address the findings in his report; a final afternoon exercise saw breakout groups address different aspects of such a plan. The following day was a MICYRN strategic planning day in which the conversation continued and a writing team was struck, to be led by Dr. Thierry Lacaze, who is bilingual, and a neonatologist and head for clinical research in Ottawa, the federal government base. Efforts were geared to have a plan developed by September 18th when the CCA report was made public. In November the report was heard officially by Health Canada and a request made for recommendations. Soon thereafter a meeting was had with the Health Minister who requested the draft business plan. A parallel exercise has engaged the support of the Canadian Child & Youth Health Coalition which brings together 10 national organizations, each with complementary mandates to improve the health and health care of young people.

2. Beyond Borders:

a. MICYRN is coordinating engagement with the USA NIH-funded Pediatric Trials Network (PTN) which obtained the agreement of NIH to expand activities in Canada, and to offer reimbursement similar to USA sites. The POPS (Pharmacokinetics of Understudied drugs) study began to recruit participants at 4 sites. The SCAMP proposal (comparative effectiveness and safety study of treatment of neonatal abdominal infections) will see an additional 6 sites open. Work involves development of a harmonized contract and budget across sites; there is strong collaboration across sites between coordinators and investigators with regular teleconferences.

b. Global Pediatric Clinical Trials Network: A strong drive from global pharmaceutical companies to see sustained infrastructure at qualified sites led to 2 meetings in Washington DC organized by Industry (Sept 9-10th) and in conjunction with the American Academy of Pediatrics (November 4-5th). It was good to catch up with Mark Turner at both, and with Irmgard at the latter.

3. Best Practices: A CIHR-Planning grant which we supported, allowed Martin Offringa (PI) to host an international meeting which has resulted in development of child-friendly additions to the trials reporting (CONSORT) and protocol (SPIRIT) statements. Irmgard attended on behalf of the EMA.

B. Rare Diseases

1. Discovery:

As of November, MICYRN's coordinating center now provides collaboration and administrative activities services to the Rare Diseases Models and Mechanisms Network which was funded $2.3M over 4 years from the CIHR Institute of Genetics and Genome Canada. Around 90 Catalyst Grants over 3 years will expedite interrogation of new genes discovered to be the cause of rare diseases. Clinicians submit applications to determine if there is a model organism scientist in the country doing work on the gene, pathway or related organelles. Catalyst grants will help to validate new gene discoveries, and suggest mechanisms for disease pathogenesis and possible therapies.

2. Data:

a. Sharing: MICYRN has been engaged as a participant in several grant proposals to national agencies. Genome Canada called for a single national network for "Sharing Big Data for Health Care Innovation: Advancing the Objectives of the Global Alliance for Genomics and Health". GA4GH (http://genomicsandhealth.org/) is an international coalition, dedicated to improving human health by maximizing the potential of genomic medicine through effective and responsible data sharing for large population cohort studies, but also rare disease research. MICYRN's federated ethics group will undertake a demonstration project on Ethics Review Equivalency.

b. Harmonization: MICYRN is partnered with the McGill-based team, Maelstrom Research (https://www.maelstrom-research.org/), which is leading international efforts in retrospective data harmonization by developing comprehensive catalogues of metadata, creating data management infrastructures aimed at leveraging data usage and harmonization, developing tools to rigorously harmonize and co-analyze data, and conducting research to improve harmonization methods. The great appeal of the Maelstrom approach is that data harmonization and analysis take place 'virtually', and it is not required for the actual data to leave its host repository or be 'pooled'. The Maelstrom tools have been used in international collaborations to study data from various rare disease registries of MICYRN-affiliated Networks (eg. CAPRI's pediatric vasculitis @ CFRI; CAPSNet's diaphragmatic hernia & gastroschesis @ Ste Justine). We are developing a demonstration project on Canadian birth cohorts). From the existing MICYRN inventory of 48 birth cohort studies, 11 independent studies representing about 32,000 records were identified that have collected similar information on environmental exposures including physical, emotional and nutritional aspects of pregnancy and longitudinal outcome focus on cardio/metabolic, and neurodevelopment measures. Harmonization will

establish information that is nationally representative across culturally and geographically diverse populations which then provides the opportunity to address expanded or new research questions not included in the original independent cohort studies.

3.3. Newcastle Children's Cancer and Leukaemia Pharmacology Studies Group (Newcastle-CCLG), Enpr-EMA category 1 network

The Newcastle CCLG runs national and European clinical pharmacology studies in childhood cancer patient populations. The main achievements of the group over the past 12 months have been as follows:

- a new national pharmacology trial to investigate age-dependent pharmacokinetic variation alongside biomarkers of toxicity in Ewings sarcoma patients (PK 2013 01) was initiated and is now open to patient recruitment in 16 clinical centres, with 24 patients recruited to date.
- clinical sample analysis from >75 patients has taken place since June, 2014, with patients recruited to 5 ongoing national/European clinical trials in addition to samples analysed for Therapeutic Drug Monitoring (TDM) approaches to patient treatment. Several new studies are also in the pipeline which will incorporate TDM approaches.
- in March, 2015, a questionnaire based study was completed, collecting information from 100 parents and children with cancer relating to their experiences in providing clinical samples/participating in research studies. The results will be published with a view to improving the experiences of future patients/families recruited to clinical research studies.
- a number of manuscripts were published from the group, including clinical pharmacology studies focusing on the treatment of children with both established and novel (Phase I) anticancer drugs (Clinical Cancer Research and Clinical Pharmacokinetics), in addition to a review of TDM approaches for the treatment of children with cancer (European Journal of Cancer) and a review of current regulations and guidance for the collection of blood samples in paediatric clinical trials (Clinical Investigation). A manuscript has also been submitted for publication reporting on the benefits of TDM approaches for the treatment of preterm and full-term neonates with the anticancer drug carboplatin. Clinical trial data have been presented at several international meetings in the US and Europe.

3.4. Pediatric Clinical Investigation Network, PedCIC, Enpr-EMA category 1 network

- Extension of French Pediatric Clinical Investigation network to 16 centers
- The network is classified level 1 and part of EnprEMA since the beginning.

The French Network of Pediatric Clinical Investigations centers started in 2000 supported by INSERM and corresponding university hospitals. In 2014, two new centers were included in **Brest and in Rennes, the number of centers being now 16**, with high potential of recruitment. The aims are to facilitate the development and availability of medicines for children aged 0 to 17 years and to ensure that medicines for use in children are of high quality, ethically researched, and authorised appropriately. The Pediatric Network is facing now increasing requests from pharmaceutical industries and is organized to conduct complex pediatric trials. Clinical research activities, activities undertaken between 2007 and 2013 were the following: .ongoing trials were 76 in 2008 and 127 in 2013, with a mean inclusion rate of 87% in 2013.

Members of the Pediatric Network: E. *Jacqz---Aigrain1 --- coordinateur (Robert Debré --- Paris), M. Bardou (Dijon), M.Castanet (Rouen), H.Chevassus (Montpellier), M. Fayon (Bordeaux,), C.Gras-*

--Leguen (Nantes), F.Gottrand (Lille), R.Hankard (Tours), B.Kassaï (Lyon), E.Merlin (Clermont--Ferrand), P.Pladys (Rennes), I.Pin (Grenoble), M. Roue (Brest), J--M. Treluyer Paris–NEM), J-P. Salles (Toulouse), J. Sizun (Brest), M. Tsimaratos (Marseille),

Structuration of the Neonatal investigation Network within the CIC Network: Extension to Europe

Over 50% of children admitted to hospital in Europe will receive an unlicensed or off- label medicine. This occurs for most drugs in preterm and term neonates. from birth up to the age of 27 days,. They represent a particularly vulnerable subgroup of the paediatric population. Whilst they account for a low percentage of the total drug use in childhood, up to 90% of products are used unauthorized or off-label in this population, especially if neonates are treated in Neonatal Intensive Care Units (NICUs). The fact that health professionals are forced to use such medicines in order to ensure that children receive adequate treatment is an unsatisfactory state of affairs within the EU.

In such context, we submitted and obtained two FP7 projects : **TINN (2009)** is to evaluate ciprofloxacin and fluconazole in neonates and **TINN2 (2011)** is to evaluate azithromycin to limit severity of bronchopulmonary dysplasia. With these two European trials, close collaboration was made possible between academia, ethical bodies, regulatory authorities and pharmaceutical companies in Europe. In France, the opportunity was taken to set-up the Neonatal group of Developmental Pharmacology and the French neonatal network under the French Society of Neonatology (www.perinat-france.org/.../sfn-societe-francaise-de-neonatalogie) The network will support initiatives of the European pharmaceutical industry. Increasing the appropriate use of medicines in children will be of direct benefit to children, their families and health professional.

1. Legrand F, Boulkedid R, Elie V, Leroux S, Valls E, Valls-i-Soler A, Van den Anker JN, Jacqz-Aigrain E. A Delphi process to optimize quality and performance of drug evaluation in neonates. PLoS One. 2014;11:9:e104976. doi:

2. Leroux S, Zhao W, Bétrémieux P, Pladys P, Saliba E, Jacqz-Aigrain E; on behalf of the French Society of Neonatology. Therapeutic guidelines for prescribing

antibiotics in neonates should be evidence-based: a French national survey.

Arch Dis Child. 2015 Jan 27

Training of clinical Investigators

Local trainings of investigators to the conduct of Clinical Trials, Good Clinical Practices, Specificities of drug evaluation in children and neonates…are organized regularly.

One day of training was organized in Paris, based on the **Grip Road show (FP7 GRiP project)**. Sixty participants from institutions and Industries, physicians, nurses or students participated.

Consensus document to optimize procedures for informed consent in children

The role of informed consent in human research is central to ethical conduct. Asking for consent in pediatrics is a complex process as informed consent has to provide parents and child with explanations to help them make educated decisions about whether to participate in a trial. The consent document should be the basis for a meaningful exchange between the Investigator and the parents and is to be used as a guide for the verbal explanation of the study. The written processes is central ethical step : the parents' signature provides documentation of agreement to participate in a study, Guidelines often recommend procedures for obtaining informed consent although requests from sponsors may sometimes exceed legal and ethical obligations and may be difficult to implement.

Within the network, we rewieved all Regulatory Requirements, Good Clinical Practices, National and International Ethical documents related to « Informed consent in children » with members of

Ethical Committees, industry members, Regulators and investigators. Consensus papers review the guidelines for obtaining informed consent and also discusses prevailing views on current controversies, ambiguities and problems with all « practical issues » related to parental consent in pediatric trials. Procedures are now implemented in the network. 20150313 Achievements of the Pediatric Clinical Investigation Network.docx

1. Legal Aspects of Consent in Children / Dispositions juridiques relatives au consentement (Part 1).

2. Pratical Aspects of Information and Consent in Children / Aspects pratiques de l'information et du consentement chez l'enfant (Part 2) by F Nacka1, L Benadjaoud2, M Fayon1, E Jacqz-Aigrain2 Pediatric CIC network

(in press).

3.5. Juvenile Scleroderma Working group of the Pediatric Rheumatology European Society (PRES), Enpr-EMA category 3 network

In the running juvenile systemic sclerois inception cohort we had an amendment, we can include now all patients with jSSc. Up till now over 40 patients are included. They are followed with a standardised assessment every 6 months. (www.juvenile-scleroderma.com)

We developed an activity score for juvenile systemic sclerosis, which is aimed to assess activity of the disease in at least 6 months long clinical trial. It was developed in three stages. In two consecutive rounds interested pediatric rheunatologist all over the world and the members of the group were asked in a survey to rank domains and items to assess acitivity of jSSc. The third round was a face to face consensus meeting of the experts to finalize a proposal in an consensus meeting set up. We are in the process to validate the proposal in the inception cohort patients.

We are in the process to develope a prospective web based registry for juvenile localised scleroderma.

3.6. SwissPedNet, Enpr-EMA category 3 network

12 June 2014

During the fPmh* congress SwissPedNet organized the 2nd edition of SwissPedNet Clinical Research Session. The research projects presented from 14 young researchers covered all disciplines of pediatrics; beside clinical and epidemiological questions also studies in basic research have been presented. With the support of three pharmaceutical companies we could offer an award of CHF 3000.- for the best presentations.

**foederatio Paedo medicorum helveticorum, "first medical lobby for children and adolescents" from the Swiss society of paediatrics, the Swiss society of paediatric surgery, and the Swiss society of childhood and adolescent psychiatry and psychotherapy.*

8 August 2014:

Collaboration SwissPedNet with the newly established Chair Pediatric Pharmacology at the University of Basel.

SwissPedNet is the ideal partner for the Swiss chair of pediatric pharmacology located at the University of Basel to succeed with the intended close collaboration of all Swiss universities and bring together all pediatric clinics.

A joint application to the Gebert Rüf call has been submitted.

25 Sep 2014:

Swiss Medical Weekly publishes a review article: "Reserach dedicated to children: SwissPedNet with its international links overcomes key barriers to proper research in paediatrics." (http://www.smw.ch/content/smw-2014-14006/)

13 Oct 2014:

The efforts of SwissPedNet to become part of the Swiss Research Infrastructures Roadmap (application submitted in January 2014 for the update of the roadmap as per 2017) were rewarded.

The Swiss funding agency considers SwissPedNet an integral part of the SCTO/CTU structure. The application will now be handled within the application of the Swiss Clinical Trial Organisation SCTO.

The amount of funds SwissPedNet will receive is now in evaluation and negotiation between all stakeholders.

25 November 2014:

SwissPedNet decided during its General Assembly to establish an advisory board with national and international experts.

As of 1 Feb 2015 SwissPedNet has an advisory board with the following members:

- Dr Saskia de Wildt, Erasmus MC Sophia Children's Hospital, Rotterdam, the Netherlands
- Prof Martin Offringa, Child Health Evaluative Sciences, The Hospital for Sick Children, Toronto, Canada
- Dr Simon Rotzler, Interpharma Switzerland
- Dr Mark Turner, Institute of translational medicine, University of Liverpool, UK
- Prof Johannes van den Anker, University children's hospital Basel, Switzerland

For the time being their main task will be evaluating the SwissPedNet annual report, judge about the activities, and support/advise the annual planning.

First meeting will be held on 19 Nov 2015.

25 November 2014:

SwissPedNet decides to support a platform for study nurses and study coordinators. The first national meeting will be held on 16 April 2015.

As the event is open also for study nurses in adult medicine, the event is jointly sponsored by SwissPedNet and the SCTO.

23 December 2014:

SwissPedNet made a survey within the clinical pediatric hubs to collect the on-going pediatric multi-center studies in Switzerland. The data has been collected during August to December 2014. Completeness of the data is not guaranteed.

We collected 85 pediatric multi-center studies open in Switzerland as of 23.12.2014.

89% are IITs / academic studies, 11% industry studies

The main part of research activity of the Swiss pediatricians lies within the realm of non-interventional epidemiological studies and the establishment of registries.

41% observational studies / 35% patient registries / 17% interventional studies / 6% clinincal experimental or translational studies, 1% biobanking

3.7. Neo-Circulation, Enpr-EMA Category 3 network

NEO-CIRC is an international consortium funded by the FP7-HEALTH programme with 18 partners from 8 countries. The consortium will study an age appropriate formulation of Dobutamine and a new definition of neonatal shock. A series of clinical trials was agreed in the Paediatric investigation Plan submitted to the PDCO of the EMA. The first observational study NEO-CIRC001A was opened for recruitment in August 2014.

3.8. TEDDY, Enpr-EMA category 4 network

Establishment of TEDDY governing bodies

The TEDDY Network officially established its governing bodies during the first General Assembly that was held in Castellaneta Marina (Italy) on October 3rd, 2014 at the Nextwork Forum (2014 edition): the Scientific Coordinating Committee (SCC) and the Strategic Planning Board (SPB), a committee aimed at ensuring the adherence to TEDDY high quality standards (please refer to attached memorandum).

Participation in the setting up of the European Paediatric Clinical Trial Research Infrastructure (EPCTRI)

Starting from January 2015, TEDDY is participating in the preparation of a proposal for a new paediatric research infrastructure (EPCTRI) devoted to implementing paediatric clinical trials and to be coordinated by Mark Turner (University of Liverpool). The proposal has been disseminated within TEDDY and as of today Italy, Poland and Albania, among TEDDY members, are candidates to participate in the RI.

Survey to map the network's expertise, competences and infrastructures

As more relevant activity, TEDDY has started an internal survey to clearly map the expertise and competences of the clinical centres participating in the TEDDY Network.

The survey will have two main objectives:

1) to collect information on paediatric clinical trials expertise and
2) to identify Partners' cross-competences that do not directly deal with paediatric clinical trials and study conduct, but involve aspects such as regulatory requirements, ethics and governance.

Results of this mapping process will be made available through TEDDY website to facilitate the contact between Sponsors of paediatric clinical trials and TEDDY research centres.

The survey will also be useful to scan the competences of possible participants in the EPCTRI, also in terms of centres availability and capacity in participating in paediatric CTs.

Website

A new improved website is being developed by TEDDY Coordinator.

Once finalised, the website will not only be a window for presenting the Network, its Partners and activities, but it will also become a service tool for facilitating the conduct of paediatric trials.

The website will in fact collect standard operating procedures for conducting clinical research in paediatrics

that will be at disposal of TEDDY members, and will provide news and updates on the paediatric research field.

Analysis of FP7 projects for paediatric drug development and participation in the European Commission public consultation

The TEDDY Network is maintaining and keeping updated a database collecting information on projects funded under FP7 to develop off-patent paediatric drugs.

On the basis of the above collected information, in September 2014, TEDDY participated in the European Commission's consultation for Horizon 2020 Societal Challenge "Health, demographic change and wellbeing" for the programming exercise 2016/2017.

TEDDY key recommendation was the renewal of funding to study off-patent medicines for children in Horizon 2020, also in consideration of the fact that paediatric off-patent medicines are not funded by any other programme, at EC or national level.