STATEMENT OF THE RETICS COORDINATOR

RETIC CODE:

RD12/0026/0001

RETIC NAME:	**RED DE SALUD MATERNO-INFANTIL Y DEL DESARROLLO**
RETIC COORDINATOR:	**ADOLF VALLS i SOLER**

INTRODUCTION

Maximum 2 pages

In Spain, mother and child care provided by the National Health System in the Autonomous Communities is excellent as guarantee by low rates of maternal, perinatal, neonatal and child mortality rates. However, new health problems emerge, derived from high rates of prematurity and multiple gestations, and the increase in childhood obesity. Analysis of the causes of morbidity and infant and maternal mortality and the various preventive and therapeutic strategies to be implemented, should be based on the best scientific evidence available. Without scientific support, any plan or intervention is ineffective and inefficient, or worse, counterproductive and economically wasteful in a time of scarce resources.
Research in the area of obstetrics, neonatology and pediatrics and the resulting scientific publications, have grown in recent years, but are still inferior in numbers and quality to those of other European countries. There is especially a shortage of quality clinical research based on large cohort studies or pharmacologic and non-pharmacologic clinical trials. We also note that in general, our investigations do not have a clear translational focus on immediate clinical application.

As a corollary to all the above, a group of neonatologists, pediatric sub-specialists, obstetricians and biologists interested in the area of Maternal and Child Health established an application research network in 2008. This initiative took the form of a request for assessment submitted to the call for Cooperative Research Thematic Networks (RETICS), convened by the Health Institute Carlos III (ISCiii).

RETICS background.

The thematic Network of Cooperative Research in Maternal and Child Health and Development (Red SAMID), was funded in 2008 by the ISCiii. The Network is currently composed of 12 research groups from 7 autonomous communities, selected through a competitive call.

A total of 110 researchers are part of the SAMID Network, including obstetricians, neonatologists, perinatologists and other pediatric sub-specialists in areas such as nutrition, metabolism, intensive care, pediatric surgery, among others, apart from groups of other health professions such as pharmacists, biologists and biochemists. We note that this is the first pediatric network devoted exclusively to research in our country.

The mission of the Network is to generate high quality scientific knowledge in an area of highly relevant socio-economic impact, in the Maternal and Child Health and Human Development area. Thus, the ultimate goal of the Network is to improve the quality of health care in these areas.

To achieve its strategic objectives, the network was equipped with a global budget for 2009-2012 of € 2.5 million, which was mainly used to hire 16 investigators, being certainly the biggest boost received ever for pediatric research in Spain.

Since its begining, the Network has focused on studying perinatal health and diseases of children and adolescents, in four key areas: prematurity and immaturity, nutrition and development, inflammation and infection, and environmental and epigenetic effects. The Network also aims toward translational research, to bring the results to clinical practice and transfer innovations generated, in the national industry; to generate added value and employment. In addition, we intend to conduct multicentric clinical trials of pharmacological or non-pharmacological interventions in pregnant women, neonates and children.

The commitment to develop in these areas was undertaken by research groups of the network, since they all had a remarkable previous scientific career, contrasted by the research contracts achieved and high quality scientific publications. (In other sections of this proposal - Document 1-, the best scientific publications, patents, funded projects and other outputs achieved by our RETICS are specified).

The Present of the RETICS.

In fact, the research groups of the RETICS are continuing their activities, but not only those planned initially for the last year of its initial funding in 2012, but also are engaged in other joint activities, possible because of additional funds from local, regional, national, European and even international private and public funding institutions had been secured.

Research Groups from our RETICS are part of Consortium of two European projects funded under the “Medicines for Children” calls by the EC´s 7th RFM, for the period 2011-2015, the GRIP and NeoCirculation projects.
The GRIP project (Global Research in Paediatrics), was funded with €6 millions, as a Network of Excellence to develop a Paediatric Pharmacology Training Program for physicians, pharmacists and nurses, and to contribute to overcome the blocks confronting the development of safe and effective medicines for pregnant women, neonates and children. The RETICS is an associate partner for the project.
The NeoCirculation project was also awarded €6 million. Its a Cooperative Research Project aiming to study, develop and help to put into the market a Dobutamine preparation for use in neonates with shock, as well as for transitional cardiovascular failure in premature infants. Two groups are part of the Consortium, one (La Paz Neonatology Group) leads the clinical trials, and another (Cruces Neonatology) is in charge of the Work Package on preclinical studies.

Another European project in the area of nutritional research on the effects of diet on mental performance of children is the NUTRIMENTHE, 7th RFP, for the period 2008-2012 (Valdecilla Group).

Regarding the design and conduct of clinical trials, our RETICS had an impressive record. In the first call on 2012 by the Spanish Platform for Clinical Trail (CAIBER), seven of the eight trials presented by our network were classified as of excellence and selected for funding. This represented the 16% of all trials selected. Some trials are part of larger trials funded at European level (NeoCirculation and SafeBoot), others have plans to be implemented in other countries (EuroNeoKiss for prevention of hospital-acquired infection, and low oxygen use for resuscitation of immature infants), and the rest were to be perform in Spain (Low-molecular-weight heparin in Eclampsia, Topiramate in neonatal hypoxic-ischemic encephalopathy, Metformin in the prevention of type 2 Diabetes and Ibuprofen for closure of the ductus arteriousus in two different strategies).

In its 4 years of existence, our RETICS has organised four Annual Scientific Workshops, in which all ongoing projects were presented and those been planed reviewed. Moreover, specific training actions to disseminate knowledge and expertise on high-quality research were developed. A Good Clinical Practices Workshop delivered by TSF Academy with accreditation from the British Medical Association was attended by 40 researchers. A Workshop on Design of Clinical Trials in Paediatrics were also organised, and attended by some 50 junior, mostly members and trainees from the RETICS research groups, but also by other interested researchers.

The Future of the RETICS.

The Consortium is now applying to this 2012 ISCiii call for proposals, this time to use the funds, if granted, to a specific Research Programme as well as a Training and Educational Programme. Comprehensive information for all the different aspects of these two Programmes is given in all detail on the different sections of Document 1. Thus, the programmes will not be again explained here. Nevertheless, a summary of some general aspects on how both Programmes interact and will be developed, and especially on other research and training activities are commented in the next paragraphs.

The Coordination of both Programmes will be performed by the same persons at the Bilbao´s Neonatology Group (BIOEF), as described, to assure there will be a good and coordinate timely development.

Further to the research actions described in the different WP, tasks and activities, our RETICS plans to continue with other successful research activities, mainly in relation to European funded projects and performance of clinical trials, seven of them already funded and running, but others will be proposed in the near future.

Regarding training, another Workshop on design of RCT in paediatrics will be organised in November 2012, and an educational session to disseminate our research activities among neonatologist and neonatal nurses will be organised, in the occasion of the X International Symposium on Neonatology in Bilbao.

We also plan to develop a Network of Excellence, which would include selected Spanish hospitals, to perform

pharmacological and non-pharmacological clinical trials on topics of interest for foetuses, neonates, infants, children and adolescents.

Finally, our intention is that the new RETIC can be the embryo for the future creation of a truly Institute for Research in Maternal and Child Health and Human Development, as existed for years in other countries like USA, UK and Finland.

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RETICS OBJECTIVES: THEIR RELEVANCE FOR THE OBJECTIVES FOR THE HEALTH STRATEGIC ACTION

Describe in detail the manner in which the proposed RETICS goals address the scientific, technical and social policies of the Health Strategic Action as stated in this call.

Maximum 1 page

In this section we provide information supporting the fact that our general (prevention of impaired neurodevelopment and obesity and the metabolic syndrome) and specific objectives previously specified are adjusted and, truly relevant towards scientific and social policies of Health Strategic Actions, as stated in the call (Official State Bulletin -BOE-, No 53, March 2, 2012, Sec. III, page 18349). Specifically, our proposal fits with the general goals of the Spanish Science and Technology Strategy, since all our activities are design to promote the health and well being of the citizenship within a sustainable development, to prevent gender discrimination by promoting the role of women in all steps of research and development (we have a high proportion of women among all researchers). Our goals are also aligned to those of the VI National Plan for Research, Development and Innovation (R+D+I) for 2008-11 period, and fits the Strategic Health Action that aims to increase knowledge, to preserve the health of the population and to promote preventive, therapeutic and rehabilitation actions for diseases, by promoting the capacity of the Health System on R+D +I.
Our objectives are closely related to the specific aims of the Strategic Health Action for R+D+I on Health by: 1) increasing the public and private economic resources, 2) incrementing the number and quality of human resources, 3) enhance the scientific productivity and international dimension, and 4) assist the transfer of knowledge and technology to the health system. We believe this alignment is proven by the details of the work program.
Furthermore, our objectives are also closely aligned to the five research priorities of the Strategic Health Action, as stated in the following paragraphs.

Line 1: Molecular and cellular technologies apply to human health. We will work in the sub-lines: 1.2 Prediction, diagnosis and follow-up of diseases and monitoring of therapeutic response (biomarkers for prediction and follow-up for specific diseases and conditions causing neurodevelopment (ND) impairment and adverse metabolic outcomes), and 1.4 Biotechnology and bioengineering of devices for monitoring and respiratory support.

Line 2: Translational research for human health. Our program covers the following subareas: 2.1. Neurologic and Mental Diseases (diseases and conditions causing adverse ND outcome), 2.2 Women health and Gender and Health (gestational conditions affecting growth and fetal well being), 2.4 Pediatrics (main focus of all actions of our network), 2.5 Aging (we are focused on the study of perinatal basis of human health and disease), 2.6 Infectious disease (meningitis and hospital-adquired infections as a cause of ND impairment), 2.8 Cardiovascular conditions (conditions causing cerebral oxygenation impairment -shock, stroke-, as well as those resulting from the appearance of the metabolic syndrome -hypertension-), 2.9 Diabetes and Obesity (obesity from early childhood to preadolescence and adolescence), and 2.14. Chronic and Inflammatory diseases (chronic conditions like Bronchopulmonary Dysplasia, hypertension..).

Line 3: Promotion of research on Public Environmental and Workers Health, Dependency and Health Services to enhance the quality of life of the Spanish population. We study different aspects of the following sub-lines: 3.1 Transfer of the research results to clinical practice on quality, efficiency of the Spanish National Health Service (NHS) and Patient Safety; 3.4 Environmental Health (studies of toxic exposure of pregnant women and their fetuses); 3.5 Dependency (severe ND impairment resulting from foetal, neonatal and post-neonatal risk factors); and 3.7 Perception, satisfaction and quality of life (the main goal or mission of our network is to contribute to the increment of the quality of life by the number of years of Spanish children) .

Line 4: Research on medicines, cellular therapies and clinical trials. Our objectives are also perfectly aligned to sub-line 4.4 Non-commercial clinical research on independent academically-driven clinical trials in generally, and specifically on orphan drugs and the paediatric population (we are performing now seven RCT and plan to develop some more, outlined in the proposal, if it is funded),
The dissemination plan for the project is described with detail : Programme coordinator form sections Impact and Transfer form and Retics coordinator form, section Potential Impact .

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POTENTIAL IMPACT

Describe the dissemination plan and the strategy for exploiting results
Describe the potential impact on Health population and Health National System
Describe the contribution of the RETICS to national and international standards

Maximum 1 page

1. Dissemination plan and strategy for exploiting results.

The details for the Dissemination Plan and Strategy as well as the explotation of results, has been already detailed in the section on Impact and transfer of document 1. Here, regarding the RETICS, a few additional details are provided, in relation to the main stakeholders. In general, our website (www.redsamid.net) will be the key source of information for parents, public in general and other researchers. For specific stakeholders:

1) General public. Dissemination of results will be performed by periodical newsletters and selected press releases of important achievements.

2) Parents and neonatal advocacy associations, The already identified associations will be contacted make them aware of projects and outputs. It is plan to involve them on clinical trials right from the planning stage in aspects like importance of studies, recruitment issues and inform consent forms.

3) Scientific community. This specific plan is in no way different from that detailed for the Research Programme, but for the fact that will include additional activities perform by the RETICS, mainly related to clinical trials, and training activities.

4) Spanish Governmental Health Institutions,Health institutions and services. Main results that might of importance in relation to clinical care and that might change practices to improve quality of care will be directly make available to those institutions. Results of clinical trials and any guidelines and protocols that might be developed will also be disseminated to them.

2. Potential impact for Health of the population and of importance to the Spanish National Health System.

It is likely that our RETICS will have results that might have a positive impact on health of the maternal, neonatal and peaediatric populations; mainly by information leading to better short- and specially long-term outcomes for preterm, and term babies with hypoxic-ischemic injuries and infants and children with brain injuries, as well as some impact on the high rates of childhood obesity.

The research activities might contribute to improvement in health, learning ability, mental capacity of the Spanish population and reduce the ongoing health and welfare costs associated with these lifetime disabilities or handicaps resulting from premature birth.

Our RETIC is putting great efforts to conduct pharmacological and non- pharmacological clinical trials within our network. Moreover, it aims to establish a Coordinating Centre to promote, design, develop and coordinate trials in Obstetrics and Paediatrics, and to promote in collaboration with the Spanish Scientific Societies in those fields, a Research Network for Clinical Trials in selected academic and not academic hospitals of excellence.

The establishment of our research network will facilitate active collaborations between partners and add value to their current activities. In addition, collaborations between other funding agencies and public and private stakeholders will be actively pursued. It can be anticipated that we could have a catalyst effect on relevant research activities and thereby enable closer integration of programmes in Spain and in Europe.

We plan to propose to the National Agency for Health Quality of the Ministry of Health, evidenced-based quality-improvement interventions in key areas as strategies directed to prevent premature birth, hospital-acquired infections in neonatal units and childhood obesity.

3. Contribution of the RETICS to national and international standards.Within our aims is to contribute to set standards of care for the maternal and infant population in Spain and in other countries, in the areas of our main research activities: prevention of brain injury leading to impairment of ND and of adverse nutritional and metabolic outcomes, like obesity, type 3 Diabetes and the Metabolic Syndrome.

Finally, we plan to propose to the Spanish Ministry of Health to implement National Registries for the outcome of assisted reproduction techniques, gestational age specific neonatal mortality and childhood obesity.

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INTEGRATION AND JOINT PROGRAM OF ACTIVITIES

Describe the Horizontal Programs and Service Platforms
Preparation of new joint projects, joint management of knowledge
Detail the complementarity with other research projects, contracts or actions financed by national or international institutions public or private

Maximum 3 pages

In this section, the integration of the different Research Groups and the joint programme activities planned are described in detail. Initially, our horizontal research programme, from the foetus to the adolescence is presented. Latter, the available platforms are outlined, the planned new collaborative projects considered, and the complementarily to other projects reviewed:

1. Horizontal Programme. The main characteristic and uniqueness of our RETICS is that it is based not on a disease or organ system but on a process, the growth and development of human beings, from the foetus to the neonate, infant and child, up to the pre adolescent and adolescent. Thus, in fact, the study of that process most necessarily be approached by a horizontal research programme. This is the reason our RETICS includes two research groups obstetrics and perinatology –experts on foetal wellbeing-, four neonatal groups –experts on neonatal diseases-, and six paediatric groups, experts on nutritional and metabolic aspects, epigenetics, and environmental toxicology, paediatric surgery and intensive care, with knowledge in those three fields.

This multidisciplinary group of researchers working together on a common research programme seems to guaranteed the fulfilment of the objectives and the dissemination of the scientific findings. Moreover, the fact that all groups have been cooperating for the last four years makes this assumption even more likely.

This horizontal approach to the study of the perinatal basis of adult health and disease is not only the more appropriated, but also the only likely to bring about important scientific and clinical important findings that could be rapidly translated into clinical practice. The composition of our network will permit to generate cohorts of children at high risk for neurologic and nutritional and metabolic adverse outcomes. The cohorts might be recruited at already in utero, by detecting foetuses with Intrauterine Growth Restriction and also with hypoxia-ischemia to be latter followed-up from the neonatal period through childhood and into adolescence. In this regard, both retrospective and prospective cohorts will be developed and maintained for the four years of this project. This approach will permit to evaluate early foetal and neonatal biomarkers for the adverse outcomes in the two main areas of the study, neurodevelopment and the metabolic abnormalities part of the metabolic syndrome.

Additionally the establishment of the prospective cohorts will permit to design randomised clinical trials in utero and at the early neonatal period for some outcomes, and on the preadolescent period for others. The possibility to conduct trials on foetuses, although posses many ethical and legal challenges, is really the “last frontier” of pharmacology, and the most necessarily to be approached. In this field, most if not all pharmacological intervention are based on observational studies on the before-and-after paradigm, but this does not guarantee the best interest of foetuses and their mothers. We have proven our capacity on this field by developing a clinical trial to evaluate the effectiveness of low-molecular-weight heparin on pregnant women with Eclampsia that has just recruited the first patients.

We plan to promote the development of clinical trials in pregnant women for foetal proposes not only in Spain but also in the whole of Europe; much like the “second wave” initiatives did in the US. This initiative was established precisely that propose; once the “first wave” achieved its goal, to promote the inclusion of women in clinical trials.

Regarding training, the same horizontal method will be used, to expose all research staff and trainees to needs, knowledge and questions in each age group, form foetuses to adolescents. As is explained elsewhere in this proposal, training is provided via workshops, informal meetings and above all short stays in other´s groups facilities to get expose to its methodologies and expertise.

It should be stress the fact that there are no similarly structured cooperative research and training network in Spain, and very few at European or international level. This innovative research approach most be highlighted.

2. Services Platforms. Several of the research groups included in our RETICS developed platforms that were available to all others in a cooperative manner. A short description of those platforms is provided now:
- Epidemiology: As has been commented, the Coordination Group maintains a Neonatal Epidemiological Unit, at the Cruces University Hospital in Bilbao, Its formed by full-time experts on clinical epidemiology, pharmacy and design of clinical trials, a bacteriologist and a biostatistician. It is closely linked to the Hospital´s Epidemiology Unit and the CAIBER unit for clinical trials, part of a 40 units´ Spanish network. It runs the EuroNeoKiss trial, a large, cluster randomise trial to evaluate a complex behavioural intervention to prevent hospital-acquired infection in very-low-birth-weight infants admitted to neonatal intensive care units.
- Molecular biology (MB). The University of Granada group has a platform of MB of high- resolution, able to analyse high volume of samples, using the Luminex 200 System built on xMAP technology that may determine up to 100 analysis in a single microplate by use of very small sample volumes, which is very important for research in children They are experts on studies of polymorphisms of altered genes and gene expression by microarrays, and the study of those altered genes using a model of adipose tissue derived stem cells and siRNA to knock down the studied genes.
- Metabolomics. The research group from the University of Cantabria, Santander working on nutrition have a potent capacity to determinate several compounds in biological fluids: fatty acids, carnitine, amino acids, organic acids, acylcarnitines, glycosaminoglycans, enzyme activities, guanidinoacetate, creatine, S-adenosylhomocysteine, asymmetric dimethylarginine, fibroblast growth factors, oxidative stress markers, etc. Its infrastructures include tandem mass-spectrometry with electrospraytriple quadrupole, gas chromatograph with detection by mass spectrometry and flame ionization detection, High-resolution liquid chromatography, spectrophotometer and fluorimeter, amino acid analyser, solid phase extraction and thin layer chromatography equipment.
- Toxicology. The group from Hospital del Mar in Barcelona has a platform design to measure pharmacological and toxic substances, especially in specific matrixes, like saliva, hair and meconium that are of much interest for the research programme because can be obtain in a non-traumatic way and are alternatives that prevent use of patient´s blood.
- Animal models. Several groups, including the hospitals of Gregorio Marañón and La Paz in Madrid, Mar en Barcelona and Cruces in Bilbao, maintain experimental facilities that can be used by all groups to test hypothesis that could be later studied in humans, in a clear translational approach. Models go from foetal, neonatal and juvenile animal models, and from rodent to rabbits, lambs and piglets.

Furthermore, it should be noted that our RETIC has just submitted an application to the EMA´s initiative European Paediatric Network for Research on Medicines for Children (EnprEMA), to be recognised and accreditated as a Network of Excellence in this field, since is the only network on this field in Spain and one of the few in Europe. Now, EuroNeoNet initiative is already recognised and is part of EnprEMA as the only Network on Neonatology established at a pan-European level.

3. Preparation of new joint projects, joint management of knowledge. The groups is already, and indeed will in the future, preparing joint proposals and projects on the key areas of this scientific programme to complement and expand the available funding to fulfil and go beyond the objectives of the present proposal. A joint collaborative scheme to manage the knowledge developed by the RETICS will also be implemented.

Regarding projects, many research groups are actively participating in European research projects briefly outline in other sections of this proposal. Moreover, a few projects are on the planning stage. As an example the EuroNeoKiss project, a project developed within our network, selected and funded by the Spanish CAIBER that has been submitted to the 2012 project call of the ISCiii and is also planned to be submitted to the next call on Health and Innovation of the EC¨7th RP on Comparison Effectiveness Research. Groups from several European countries and different areas of expertise (medical economics, preventive medicine, and clinical epidemiologists with specific experience on clinical trials and quality improvement, patient-cantered and implemental research) as well as nursing and parent advocacy associations have already agreed to join the Consortium.

A project with participation of neonatal groups has just been submitted for funding to the DG SANCO 2012 call for projects as an Operating Grant to maintain active the European Neonatal Network (EuroNeoStat/EuroNeoNet) in 2013. A new application on this field is planned to be submitted in early 2013 call for projects.

In the research areas of obstetrics (IUGR), neonatology (Cerebral Palsy), paediatric intensive care (traumatic brain injury) as well as in nutrition (prevention of childhood obesity and type 2 Diabetes), among other, we have lead to the initiation of personal contacts to participate in upcoming European and international calls are in progress.

With regard to the joint management of knowledge, the RETIC is in a good position to disseminate its outcomes to the Spanish scientific and clinical communities, and thus to to be able to accomplish its transfer that to clinical practice, as evidence-based good and safe clinical practices to improve patients health and well being.

4. Complementarily on our network activities with other research projects, financed by national or international public and private institutions. As prove of the solid research background and scientific level of each research group and the RETICS as a whole, the complementarily of our research activities with other already financed projects will be provided in the next paragraphs in the different medical:

- Perinatology. In this subarea of research, our network participates in many financed project, since several research groups have wide experience, many scientific contacts and are well recognised as experienced researchers giving the RETIC wide exposure and a key role at an European level.
  - EuroNeoStat I and II projects. Those DGSANCO funded projects are directed to perform benchmarking for quality improvement of care, and to develop clinical trials in immature infants. Lead by the Bilbao and by the Madrid´s 12 de Octubre Groups with the participation of more than 60 Spanish neonatal units.
  - SCPE Registry. Also a DG SANCO funded project lead by the 12 de Octubre Group. Its aim is to study Cerebral Palsy by standardising its definitions and keeping a European-wide registry.
  - GRIP project. Was funded by the 2011 call of the EC´s 7th RP, as a network of Excellence to enhance the development of safe, efficacious and appropriate medicines for infants and children at an European and international level. The Bilbao group as co-leader the project´s neonatal Work Package, and the RETICS is an affiliated partner.
  - NeoCirculation. Also funded by the 2011 call of the EC´s 7th RP as a collaborative project to develop a neonatal preparation of Dobutamine. The La Paz neonatal group leads the Clinical Trail WP, and the Bilbao group the preclinical evaluation of the drug.
  - Safeboot La Paz Neonatology, funded both in Netherlands and by CAIBER in Spain. Lead in Spain by the La Paz Neonatology Group. It hypothesised that knowledge of the cerebral oxygenation measured by infrared spectroscopy will improve the neurodevelopment status at two years of age in very immature infants.

- Nutrition and Metabolism. In this topics several groups indeed have an important role in several European projects on prevention of obesity:
  - Identification and prevention of dietary- and lifestyle-induced health effects in children and infants" (IDEFICS). Financed by EC´s 6thRP on its 2004 call on Food. Universidad de Zaragoza.
  - European Recommendations Aligned (EURRECA).Financed EC´s 6th call on Food. Universidad de Zaragoza.
- European energy balance research to prevent excessive weight gain among youth (ENERGY). Financed by the EC´s 7thRP call on Health. Universidad de Zaragoza.

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ORGANIZATION AND MANAGEMENT

Maximum 2 pages

The management structure proposed is based on a multi-level organisation that balances:
- fulfillment of the work plan per se.
- attention needed on critical activities that aim to ensure the achievement of milestones and that contribute to strategic objectives.
- relationships among partners, including conflict resolution and consensus.
- quality and efficiency of all the project activities carried out.
- follow-up and fulfillment of administrative and financial issues with the funding agency, ISCiii.

The management structure of the project is closely connected to its Scientific Coordination and therefore the overall organisational structure and management procedures will benefit from this structure that has been designed with the following components:
1. Network Governing Council (NGC): A body gathering all 12 partners participating in the programme with decision making responsibility in matters affecting the overall strategy and composition of the Consortium.
2. Executive Board (EB): An executive body comprising Work Package leaders, including the Scientific Coordinators, with decision powers on technical development, work plan updates and dissemination plan.
3. Scientific Coordination (SciC): A key role in charge of the global scientific leadership, quality assurance policy and assessment of the project.
4. Project Management Team (PMT): A management team for daily management of the project.
5. External Scientific Advisory Board: An independent advisory board will be established to provide input on the scientific aspects of the projects which will also be included in the annual report to the Commission. The same body will also assist the Executive Board for ethical and data protection issues.
6. Work Package Leaders (WPL): Leading participants of each work package.

This structure will be complemented as needed with ad-hoc working groups to deal with issues that require particular attention or expert's advice.

1, Network Governing Council (NGC). A general assembly of all project partners will be set up, chaired by the RETICS and Scientific and Training Programme Co-ordinator. It will be a decision-making body dealing with issues affecting all participants and/or the project as a whole, such as overall strategy and all other matters that the Executive Board (EB) opts for referring to a higher level. It will overview the management structure, and the decision-making principles and responsibilities of all management bodies. It will also have the right to propose amendments to such structure as the project progresses. Typically, the NGC will deal with major amendments to the work plan

For decision-making purposes, each partner in the project will have one representative and one vote in the NGC. NGC members will be required to have the authority to make decisions on behalf of their respective organisation. Two thirds of the project partners attending a NGC meeting will constitute a quorum. Simple majority of the attendants will be sufficient for decision adoption. In the event of a tied vote, the RETICS Coordinator will have an additional vote. NGC meetings will be regularly held at least every six months.

2. Executive Board (EB). An Executive board will be established consisting of WP Leaders plus the Project Manager, and chaired by the RETICS Coordinator. EB members will be required to have the authority to take corrective actions as necessary within their respective organisations. The EB will be an executive body responsible for decisions regarding the project development, or that must be dynamically made to avoid endangering research and training programmes objectives. In particular, changes in the work plan will be a prerogative of the EB. It will also be able to make recommendations regarding any other project issue, including evolution. It will also monitor and review the progress of the programmes, ensure that objectives are met. For these purposes, will meet at least every three months, either face-to-face or via Internet or teleconferences.

The EB will be allowed to require specific actions or reports from the project manager (PM) and/or WPL in order to solve any issues that cannot be clarified or agreed at a lower level. These include in particular resolution of disagreements, as well as situations in which the project efficiency might be endangered. At the initiative of any of its

members, the EB will also be able to constitute committees for matters that require specific attention (such as particular scientific problems/areas, training, etc.), and to establish working procedures for such committees. For decision purposes, each member of the EB will be allocated one vote. Two thirds of the participants attending a meeting of the EB will constitute a quorum. Simple majority of the attendants will be enough for decision adoption. In the event of a tied vote, the RETICS Coordinator will have an additional vote.

As regards to communication, a Consortium communication policy will be established, making extensive use of electronic resources. The EB will take care of the definition and execution of a Dissemination Plan to ensure an effective communication with major stakeholders.

3. Scientific Co-ordination (SciC) This position will be decided at the first NGC meeting. The SciC main task will be to ensure that the work is technically performed according to the overall strategy by:
• Detecting any potential risk factors
• Following up that the expected deliverables and milestones are accomplished with the maximum quality level and that the work is implemented within the expected start and end dates
• Ensuring that each participant fulfils their commitment to each Work Package in direct collaboration with the Work package leaders
• Calling for establishment of a Corrective Action Plan, if one is warranted, to the EB.

4. Project Management Team (PMT) As the partner responsible for management, BIOEF, represented by Prof Valls-i-Soler will appoint a PM which will support the SciC to follow-up activities and monitor compliance with the work plan, planned resources and time schedule. The PMT will also support WP Leaders in day-to-day management, promoting synergy and efficiency throughout. It will facilitate communication among partners, ensuring timely delivery of the project deliverables and tracking milestone achievements. The PMT will also drive risk management (identification, assessment of threats and opportunities, mitigation and contingency plans), and will manage quality control procedures on deliverables. It will deal with partnership management and relationships with external collaborators. It will closely co-operate with the SciC and WPL in periodic reporting. The PMT will be responsible of overall financial management of the resources assigned for Coordination and Training (cost control and justification, budget management, payments control), supporting the EB in administrative tasks. Finally, it will support meetings organisation and the production of the corresponding minutes.

5. External Scientific Advisory Board (ExAB) The ExAB, with consultative functions, will be formed by independent experts external to the project, so that the expertise and knowledge could assist the EB on scientific and technical grounds. In addition to monitor scientific aspects of the project, will oversee ethical issues for all activities. The ExAB will hold annually teleconferences.

6. Work Package Leaders (WPL), Each WP is the responsibility of one or two partners, as per the work plan. WPL will ensure permanent follow-up of activities, in direct contact with involved participants and will report on a quarterly basis to the SciC. The WPL will have responsibility for day-to-day management of specific work related to individual WP. This includes implementation of the WP tasks as defined by the Work Plan, resolution of technical problems, follow-up and coordination of the participants involved, production of the corresponding outputs, and delivery to the PMT, preliminary identification of risks and reporting of progress against the plan.

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FORMATION AND COORDINATION PROGRAMME

Describe the objectives, activities scheme, evaluation of results plan and budget coordination.

Maximum 2 pages

Training Programme objectives.

The main aim of the Training programme is to enhance the research activities of all RETICS members, to promote the development of hypothesis-driven high quality research within and outside the RETICS, in the main areas of the RETICS scientific Programme, namely the prevention and clinical management of impaired neurodevelopment and adverse nutritional and metabolic from the foetus to the adolescent.

More specifically, all training activities developed and carried on by the RETICS related to its main areas of its Research Programme will be focused on methodology and technical skills needed to design, develop, perfume and publish high quality research. In this regard, activities will cover the following areas:

1) Epidemiological methodologies. It will include training courses or workshops on the following areas: design and performance pharmacological and non-pharmacological clinical trials in perinatology and paediatrics (methodological, ethical, legal and regulatory aspects), training to design and conduct non-interventional, high-quality epidemiological studies, data management and statistical analysis, design of a research protocol and a proposal for peer-review funding...

2) Analytical methodologies. It will include exposure to different methodologies used for the measurement of specialised techniques related to different system functions (cerebral activity and oxygenation...), cellular (flow cytometry...), sub-cellular (biochemical, haematological...), molecular analysis (PCR...), imaging (PET...), among others

3) Experimental models. Basic methodologies in foetal and juvenile animal models of interest and related to the main areas of the RETICS´ objectives: neurodevelopment (foetal growth restriction, exposure to different toxic environmental or drug substances and hypoxic-ischemic insults, neonatal and post neonatal brain insults (brain trauma, hypoxia-ischemia, lung insufficiency of different aetiology, shock...).

Scheme of the Training Programme.

The global aim of this program is to try to achieve a greater involvement of all RETICs members in other Research Groups' activities and obtain an interdisciplinary knowledge to all RETICS full members, contracted research personnel and trainees by providing training in topics related with RETICS Scientific Program´s objectives and research activities. This will be achieved through the following actions:

1) Mobility Program. The aim of this Programme is to facilitate the interaction between individuals of the RETICS Research Groups, in order to improve the technical skills and scientific capabilities and to learn new techniques and methodologies. Moreover, this will allow research to keep in touch with different research environments, increase their scientific knowhow and expand their contacts,

An application form will be available for all RETICS' members. The applications will be evaluated by the Training Committee, taking into account the interest of the stay for the researcher and his/her group within the RETICS objectives.

2) Attendance to Courses and Conferences. The main goal is to facilitate the involvement of RETICS researchers in course and conferences organized by external groups, in order to share the research conducted through the RETICS and provide researchers in training to obtain the necessary experience to present their research in public.

Financial assistance could be provided to all RETICS´s members for registration fees, travel and maintenance to attend courses and other educational activities, as long as are considered of interest for the RETICS objectives, Democratic rules for transparency to assure equal opportunities for all possible applicants. Applications by trainees and personnel hired by the RETICS will be prioritised for funding.

3) Workshops, Courses and Symposiums organised by the RETICS. The RETICS will collaborate with other partner in the organization of international symposiums related to the main topics of the RETICS Scientific Programme. All symposiums and different training courses will be open to RETICS´ researchers as well as to other individuals and groups interested in the topics. No registration fees will be set for RETICS' members

Apart from that, annually, the RETICS will organise a Workshop in order to discuss and share the advances in all research activities of the RETICS. Young investigators will be invited to deliver oral presentations of their research activities to facilitate their active role in these meetings and to generate synergies with persons from other groups.

4) Evaluation of these training activities. All training program activities (courses, conferences, workshops, symposiums,…) wll be reported in the RETIC´s Project manager to be displayed in the RETICS´ website for dissemination to all interested stakeholders.

In order to evaluate the results of the program each researcher who performs a training activity will complete a short report in a predesigned template form that will include a summary of the activities, attendees, and an evaluation of the activity survey by assistants in a standardised RETICS template, In addition, after each annual workshop the Coordinator, through the Project Manager, will perform a summary of activities developed during the workshop that will also be displayed in the RETICS´ website.

The Coordinator will prepare a summary of activities at the end of each year. Moreover, every two years he will evaluate the fulfillment of Training Program goals through preset indicators such as: personal staff involved in training activities compared with the number of RETICS´ Research Groups, number of oral presentations by researchers in training in congress, conferences and RETIC ´s annual workshop, among others.
Training Programme Coordination.

The RETICS' Coordinator, Prof. Adolf Valls-i-Soler has been elected by unanimity by the RETICS´ members and will represent the Consortium and negotiate on its behalf, if necessary. The RETICS' Coordinator together with the Executive Board will be responsible for the effective overall execution and implementation of the Training Program. The Executive Board will be constituted by 4 members: RETICS´ coordinator, Training Program Deputy Coordinator, to be elected, and two Groups' leaders, also elected between RETICS´ Research Groups. The RETIC Coordination will be the Executive and Training Committees chairperson. There will be two yearly meetings. The Executive Board will be directly advised by an External Scientific Committee.

The RETIC Coordinator will be supported on all administrative tasks by a Project Manager that will be directly responsible for all communication with the Groups and the ISCiii, the funding agency.

All actions and decisions regarding the Training Programme will be taken in accordance with full transparency under democratic rules.

Evaluation of the results of the Training Programme .

The results of the Training Program as well as its timely development according to the detail plan established will be evaluated by the Training Committee, other the leadership of the Deputy Coordinator. In case of significant deviations from the preset plan, it will make proposals to the RETIC´s Coordinator to propose corrective actions that will be taken after consultation with the RETIC´s Executive Committee.

Budget for the Training Programme,

The budget assigned for this program is approximately of € 10.000 for the first year of 2013. An annual increment of 20% has been planned, representing a bit over 1.7% of the total annual RETICS´ budget. We are fully aware that this is a much limited budget that constrains the development of the trainings activities that would be required. For this reason, great efforts will be dedicated to identify possible alternatives sources to complement the RETICS' Training Programme activities.

Possible sources for funding the RETIC´s activities could possible come from public funding agencies at European level (DG SANCO, EC´s Tempus programme...), Spanish national level (ISCiii, Health and Finnancial Ministries...) or Spain´s autonomous regional level (Health and Educational Departments...). Moreover, privet institutions at all previous mentioned levels (Research and clinical funding organisations, Pharmaceutical industries, Clinical and Laboratory manufactures and providers...).

Training Program budget coordination. The RETICS Training Programme Board, through the Project Manager will be responsible for the management of the budget dedicated to training, financial coordination, preparation of an annual report of activities, preparation and dissemination of meeting and funding calls and requirements for the proper operation of the RETICS external relations and partner liaison, coordination of training activities, final report, and the coordinating of meeting agenda and arrangements.

Moreover, the project manager will be responsible of continually updated and maintained RETICS website (www.redsamid.net). This website will become the central source of project information for parents, the public, the project partners as well as other researchers and stakeholders. All RETICS documents will be posted to the Intranet Area of the website, which only partners can access. This ensures that all partners have immediate access to the most up to date versions of all important RETICS documents.

RETIC CODE:
RD12/0026/0001

Add an image as annexe (if you wish) (formats: gif, jpg)

Maximum 1 image