RICORS SCIENTIFIC PROPOSAL

RICORS Code
RD21/0012/0001

Thematic area:	Primary care, chronicity and health promotion
RICORS name:	PRIMARY CARE INTERVENTIONS TO PREVENT MATERNAL AND CHILD CHRONIC DISEASES OF PERINATAL AND DEVELOPMENTAL ORIGIN
RICORS Leader:	Elisa Llurba Olivé
Applicant institution:	Institut d'Investigació Biomèdica Sant Pau (IIB-Sant Pau)
Work institution:	Hospital de la Santa Creu i Sant Pau
Requested budget:	2.781.900 Euros

List of PI Participants (only research groups)

Nº	Family Name	First Name	Work Institution	Region / CC.AA.	PI Clinical Activity	Nº of Members
RG1	Llurba Olivé	Elisa	Hospital de la Santa Creu i Sant Pau	CATALUÑA	YES	11
RG2	Boronat González	Núria	Hospital Universitario y politécnico la Fe	COMUNIDAD VALEN	YES	11
RG3	Cabañas González	Fernando	Hospital Universitario La Paz	COMUNIDAD DE MA	YES	15
RG4	Pallás Alonso	Carmen Rosa	Hospital 12 de Octubre	COMUNIDAD DE MA	YES	10
RG5	Gómez Roig	Maria Dolores	Hospital Sant Joan de Déu	CATALUÑA	YES	9
RG6	García Algar	Óscar	Hospital Clínic	CATALUÑA	YES	10
RG7	López-Herce Cid	Jesús	Hospital Gregorio Marañon	COMUNIDAD DE MA	YES	15
RG8	Rodríguez Martínez	Gerardo	Hospital Clínico Universitario de Zaragoza	ARAGÓN	YES	14
RG9	Larqué Daza	Elvira	IMIB - Virgen de la Arrixaca	REGIÓN DE MURCIA	NO	7
RG10	Loureiro González	Begoña	Hospital Biocruces	PAÍS VASCO	YES	8
RG11	Mesa García	Maria Dolores	Universidad de Granada	ANDALUCÍA	NO	8
RG12	Rodríguez-Núñez	Antonio	Hosp. Clinico Universitario de Santiago	GALICIA	YES	5
RG13	Rey Galan	Corsino	Universidad de Oviedo	PRINCIPADO DE ACT	NO	8
RG14	Cabero Pérez	Mª Jesús	H. Marques de Valdecilla	CANTABRIA	YES	7
RG15	Marre Cifola	Diana	Universitat Autònoma de Barcelona	CATALUÑA	NO	11
RG16	Couce Pico	Mª Luz	Hospital Clínico Universitario de Santiago de Compostela	GALICIA	YES	5
RG17	Fernández de la Llama	Patrícia	Fundació Puigvert	CATALUÑA	YES	5
RG18	Herraiz García	Ignacio	Hospital 12 de Octubre	CASTILLA - LA MANC	YES	7

RG19	Martínez Martínez	Leopoldo	Hospital Universitario La Paz	COMUNIDAD DE MA	YES	5
RG20	Martínez Orgado	Jose Antono	Hospital Clínico San Carlos	COMUNIDAD DE MA	YES	5

RICORS Code	RICORS Leader:
RD21/0012/0001	Elisa Llurba Olivé

List of PI Clinical associated groups

Nº	Family Name	First Name	Work Institution	Region / CC.AA.	Nº of Members
CA1	García-Muñoz Rodrigo	Fermín	Complejo Hospitalario Universitario Insular Materno-Infantil (Las Palmas)	ISLAS CANARIAS	10
CA2	Goñi Orayen	Concepción	Complejo Hospitalario de Navarra, SNS-O	COMUNIDAD FORAI	8
CA3	López Vílchez	Mª Ángeles	Hospital del Mar - PSMAR	CATALUÑA	11
CA4	Remesal Escalero	Ana	Hospital Universitario de Salamanca	CASTILLA Y LEÓN	6
CA5	Vela Martínez	Eva	ASSIR Dreta (Institut Català de la Salut)	CATALUÑA	10
CA6	Palasí Bargalló	Carme	EAP Sardenya	CATALUÑA	6
CA7	Maiz Elizarán	Nerea	Hospital Universitari Vall d'Hebron	CATALUÑA	12
CA8	González Mesa	Ernesto	Hospital Regional Universitario de Málaga	ANDALUCÍA	8
CA9	Martino Alba	Ricardo Javier	Hospital Infantil Universitario Niño Jesús	COMUNIDAD DE MA	6
CA10	Tubau Navarra	Albert	Hospital Universitari Son Llàtzer	ISLAS BALEARES	10
CA11	Comas Gabriel	Carmen	Hospital Germans Trias i Pujol	CATALUÑA	14

CA12	Ginovart Galinana	Gemma	Hospital Germans Trias i Pujol	CATALUÑA	10
CA13	Mengual Gil	José Maria	Centro de salud Delicias Sur (Previnfad)	ARAGÓN	10
CA14	Ramos de Luís	Anna	ASSIR Guinardó	CATALUÑA	5
CA15	Trujillo Fagundo	Alberto	Hospital Universitario Dr. Josep Trueta de Girona	CATALUÑA	5
CA16	Barrios García	Margarita	Centro de Salud de Armilla (Granada)	ANDALUCÍA	5
CA17	Carrasco Beltrán	Francisco David	UGC Dr. Cayetano Roldán (San Fernando, Cádiz)	ANDALUCÍA	4
CA18	Carreras Gonzalez	Eduard	Hospital Transfrontarer de la Cerdanya (Girona)	CATALUÑA	6
CA19	Muñoz Avellana	Begoña	Hospital Sant Joan de Reus (Tarragona)	CATALUÑA	4
CA20	Copegui Valero	Rosa Maria	Hospital Son Espases (Palma de Mallorca)	ISLAS BALEARES	4
CA21	García Vera	César	Centro de Salud José Ramón Muñoz Fernández (Zaragoza)	ARAGÓN	10
CA22	García Pintor	Sandra	Centro de Salud de El Ejido (Almeria)	ANDALUCÍA	3
CA23	Abeleira Carballo	Irene	Centro de Salud Nicolás Peña (Vigo)	GALICIA	20
CA24	Araujo Lorenzo	Patricia	Centro de Salud Ponteareas (Pontevedra)	GALICIA	3
CA25	Muñoz Sellés	Ester	ASSIR Osona	CATALUÑA	5
CA26	González del Valle	Pedro Lozano	Hospital Universitario Quirón Salud (Madrid)	COMUNIDAD DE MA	8
CA27	Valle Morales	Leonor	Hospital materno-infantil de Las Palmas de Gran Canaria	ISLAS CANARIAS	8

RICORS Code	RICORS Leader:
RD21/0012/0001	Elisa Llurba Olivé

BACKGROUND

Importance and scope of the programme at national and international levels; burden of disease mortality and mobility and disability; state of the art in Spain an in the international context.

Max. 3 pages (15,700 characters)

1. Pregnancy as a window of vulnerability: It is well known that the influence of exposures during pregnancy is not limited to reproductive and childhood outcomes, and can extend over a lifetime, embodied by the Developmental Origins of Health and Diseases (DOHaD) theory. DOHaD suggests exposures *in utero* may permanently change the body's structure, physiology and metabolism, and such changes can promote disease long after the environmental exposure has ceased. There is increasing evidence that intra and extrauterine factors (including epigenetic changes, maternal nutrition, lifestyle, newborn catch-up growth, inflammatory status, cord microbiota and chemical exposures), affect the maternal-fetal unit, and act as modulators of peri and postnatal adverse phenotypes. Therefore, promotion of maternal and child health is one of the top five health objectives of the World Health Organization (WHO), and one of the main Global Sustainable Development Goals (SDGs; United Nations, 2015) that encompasses development from birth to young adulthood (SDG 3 and 5).

2. Why placental complications (preeclampsia and low birth weight) are important? Low birth weight (LBW, birth weight <2500g) is an indicator of impaired fetal growth. Each year an estimated 20 million LBW infants are born worldwide, accounting for about 15% of all births (WHO, 2011). LBW has been associated with poorer health and development in children, and also with adverse health outcomes later in life. It is directly or indirectly responsible for 60-80% of neonatal deaths and is associated with higher risks of infection, growth and developmental delay, and mortality during infancy and childhood (WHO, 2011). At the same time, LBW has been related to enhanced risk of noncommunicable diseases (NCDs) such as of ischemic heart disease, chronic hypertension, insulin resistance/metabolic syndrome, and chronic kidney disease in adults. Impaired fetal growth is therefore accompanied with considerable burden on individuals, families, and society. Preeclampsia (PE) remains one of the most prevalent complications of pregnancy. Recent statistics show that it may affect ~5 -7% of pregnancies in Europe, and approximately 5% in Spain. Although improved obstetrical care has significantly diminished maternal mortality, it still remains a leading cause of peripartum morbidity, and a major cause of prematurity. In severe cases of PE, serious complications can occur during pregnancy and puerperium, such as pulmonary edema, cerebral hemorrhage, hepatic insufficiency, renal failure and even death. Severe PE is directly related to maternal cardiac injury characterized by cardiac remodeling, decreased myocardial relaxation and global left ventricular diastolic dysfunction. In addition, it is known that cardiovascular (CV) lesions are not limited to the gestational period but evolve after delivery. CV dysfunction evidenced by echocardiography has been found even in normotensive patients with history of PE.

3. Why maternal Preeclampsia and Cardiovascular disease? Cardiovascular disease (CVD) is the leading cause of death in women in the Western world. Despite improvement in diagnosis and treatment, morbidity and mortality are high, especially in women, since the characteristics and physiopathology in the female gender is different than in the male gender. Multiple epidemiological studies have shown that PE is associated with development of hypertension, myocardial infarction, cerebrovascular disease, renal complications and vascular and metabolic dysfunction years after pregnancy. These studies show 2 to 4 times higher risk of developing CVD in the short and long term. When PE is accompanied by preterm birth and/or small for gestational age (SGA), the adjusted risk for CVD increases 45% (95% confidence interval, 1.24-1.71) at 5 years post-partum. Therefore, history of PE has recently been incorporated by the American Society of Cardiology as an independent risk factor to indicate clinical follow-up. Cardiovascular risk management guidelines emphasize the need for prevention of CVD in women, and recent data supports CV follow-up of women with a history of PE, starting within the fourth decade of life.

4. Environmental pollutants, noise and green spaces and perinatal complications: Air pollution is one of the most studied environmental exposures during pregnancy. This exposure has been associated with several pregnancy complications and adverse pregnancy outcomes, but it has been more consistently related with impaired fetal growth. A number of systematic reviews and meta-analyses of available literature have related maternal exposure to air pollution with different indicators of impaired fetal growth such as LBW or SGA. Accordingly, the latest report of the GBD attributable to ambient air pollution has suggested that its impact on LBW could be included in future estimations of air pollution related GBD, given that it meets GBD inclusion criteria.

5. Prenatal exposure to alcohol and other substances of abuse: The use of licit and illicit drugs by pregnant women may

cause multiple complications for both the fetus and mother. Although the placenta acts as a barrier to protect the fetus from toxic chemicals present in the mother, it has been shown that most drugs used by the mother during pregnancy cross the placenta and reach the fetus. These compounds may induce changes in placental morphology, by altering angiogenic and endothelial factors and even alter placental function by modifying biochemical pathways involved in hormone synthesis. Therefore, our network would work towards providing guidelines to improve recognition, education and prevention and treatment to overcome the barriers that exist in relation to use of licit and illicit substances during pregnancy and potentially avoiding deleterious effects in fetal development and in maternal health.

6 Impaired neurodevelopment (prematurity, intrauterine growth restriction (IUGR), perinatal hypoxia): Prematurity is the first cause of morbidity and mortality in the neonatal and infant period and constitutes one of the most relevant health problems worldwide. At present, approximately 8% of all newborn infants are born prematurely (<37 weeks' gestation). Of these, 1.2% are very preterm (<32 weeks' gestation) with the rest considered "*Late Preterm*". A significant number of survivors pertaining to the *Late Preterm* group are still affected by neurodevelopmental and sensorial problems. Reduced expressivity of these developmental problems during the first months after birth prevents early diagnosis and worsens prognosis. Thus, it will not be until later stages in life, preschool or school ages, when altered neurodevelopmental or sensorial functioning become openly manifest. However, despite the body of literature accumulated, little attention has been paid to this group of infants because: (1) the general belief of neonatologists and primary care pediatricians is that this group of babies don't have long-term deficits; (2) the rate of *Late Preterm* infants that represents 6-7% of all the babies born in Spain, amounts between 24,000 and 28,000 babies/year. This number of patients overwhelms the capacity of the established follow-up programs in the Neonatal Departments of tertiary centers. Thus, due to high risk of neurodevelopmental, sensorial, executional and behavioral deficits in this population, it is imperative to establish strategies for specific follow-up programs targeting this situation, mainly developed for and accomplished by primary care pediatricians and nurses with the support of highly specialized neonatologists, and other group of specialists. Consequently, every health area must be endowed with a follow-up program that includes preterm infants and all health professionals involved in the care of these very vulnerable patients. The aim of this follow-up program should be full integration of ex-preterm infants within family and society, and development of all their potential.

7. Development of early-primary care tools for the identification of children at risk for neurodevelopmental disorders: Recent studies performed by the Spanish Neonatal Society (SENeo) have shown an increase in the incidence of extreme prematurity (<28 weeks gestation), increased survival of these extremely low birth weight infants (ELBW) but morbidities have plateau. Preterm and very low birth weight infants (<1,500 g) are at risk of developing short and long-term complications such as cerebral palsy, cognitive deficits, visual or hearing impairments, cardiovascular and respiratory diseases, gastrointestinal problems and other conditions that can alter their life course and their capacity to work in adulthood. In addition, newborns who suffer severe acquired diseases; congenital malformations or rare diseases have also prolonged hospital stay and, therefore, face similar burdens and challenges. Nowadays there is a lack of multidisciplinary and transversal follow-up that hampers potential improvement of children conditions. Identification of children at higher-risk of neurodevelopmental and sensorial disorders and establish a conjoined follow-up implicating families, primary-care pediatricians and neuro-pediatriacians is a major aim of this project, thus early and directed interventions are know to change the course and progression of neurological sequels.

8. Maternal breastfeeding and children development: Human milk is recognized as the ideal food for all infants due to its proven benefits on the health of the mother and child. The WHO and other organizations recommend exclusive breastfeeding for the first six months of life, and at least up to two years of age, supplemented with other foods. There is robust evidence of the protective effect of breastfeeding on health of a child and its mother related to fourteen diseases: nine childhood diseases (i.e., acute lymphocytic leukemia, ulcerative colitis, infections, sudden infant death syndrome) and five maternal diseases (i.e., breast cancer, ovarian cancer, myocardial infarction). If WHO recommendations related to breastfeeding were fulfilled in the US, there would be 3,340 fewer annual deaths: 2,619 women and 721 children. In Spain, there is little official information on breastfeeding rates. The latest data dates back to publication of the Annual Report of the National Health System 2012, that collected information from 1995 to 2011. Exclusive breastfeeding rate at 3 months was 66.5%, and at 6 months reached 47%. This suboptimal breastfeeding is a major public health problem. Since women currently have very short maternity leaves, support for breastfeeding should be carried out mainly from primary care. Therefore, one of our network's main objectives is promoting breastfeeding till up to two years of age in the primary care setting, to improve maternal and child health.

9 Early nutrition and metabolic disease in at risk neonates: Most infants who are SGA (up to 85%) experience a spontaneous recovery of growth (catch-up). This catch-up growth (CUG) produces remodeling of body composition and

adipose tissue development, regardless of the presence of obesity. Individuals born SGA, especially those with marked and rapid CUG, are at risk for developing endocrine -metabolic disorders. Rapid CUG in the first years of life may be responsible for subsequent metabolic alterations like metabolic syndrome, type 2 diabetes, higher cholesterol and CVD. Higher blood pressure was reported in a group of term infants fed with nutrient-enriched formula (28% more protein). In Spain, the Aladino study (2019), which analyzed prevalence of obesity and overweight schoolchildren aged 6 to 9 years, shows worrying figures: 4 out of 10 of schoolchildren are overweight. From these, 23.3% correspond to overweight and 17.3% obesity. Maximum prevalence of obesity was 14.5% at 7 years of age in girls and 14% in boys, with overweight prevalence of 26.8% at 12 years. Another aim of this project is to evaluate the impact of lifestyle strategies to improve cardiovascular and metabolic health in those children with IUGR, maternal diabetes, obesity) in the community level.

10 Long-term sequelae of children with serious chronic diseases: Several diseases as accidents, cardiac arrest, trauma, pediatric stroke, cardiopathies, cardiac surgery and respiratory chronic diseases are risk factors for major neurodevelopmental impairment and psychological, visual, auditory disabilities in childhood. Although survival has improved, the number of long-term technology dependent children is progressively increasing. Multicenter registries are needed to improve knowledge of these diseases. Management of these patients has to be multidisciplinary, including Primary and Hospital Care, families and organizations integrating preventive measures, early detection, medical and social long-term follow-up assistance in home care programs. Ethical analysis and palliative care are important issues in management of these chronic patients. New methods for education by simulation and telemonitoring, and telemedicine follow-up could reduce complications, hospitalizations and improve children and parent satisfaction.

11 Aligning research and innovation with gender and children values, needs and expectations: Responsible research and innovation (RRI) require researchers, citizens, policymakers, businesses and third sector organizations to work closely together. Health inequalities have become recently one of the major concerns of European health policy. Clinical and epidemiological research document male-female health differences, trying to explain them within bio-medical models. However, a part of biological (sex) divergence, health inequalities reflect differences in social roles, social status and culturally established patterns and stereotypes of femininity and masculinity (gender differences). It is also considered that inequalities that affect women also affect children, not only as second victims of maternal health, but due to lack of investment in new therapeutic strategies for children with chronic diseases. According to the Convention on the Rights of the Child (UNCRC), children have the right to participate in their own healthcare and make their voice heard. Children's opportunities for understanding their conditions, sharing their views and participating in decisions regarding their care, depend on healthcare professionals but also on parents' ability to communicate and include them. One of the major limitations is lack of coordination between different care settings for prevention, early detection and monitoring of evolution and sequelae of childhood chronic serious diseases. Therefore, the Consortium plan to include patients' experiences and point of views in the design of policies to improve different aspects of maternal and children health.

12. Inclusion of e-health technologies to improve detection and follow-up of different maternal and children chronic conditions, at the primary care level: Electronic health (eHealth) provides solutions for patient empowerment and value-based health care. The pregnant patient seems to be a prime candidate for eHealth-supported care with telemedicine for fetal and maternal conditions. Previous studies in pregnancy show that eHealth applications are good alternatives to standard practice. In the pediatric population, evidence supports the use of behavioral eHealth interventions in treatment or prevention of pediatric physical health problems that involve health behaviors. eHealth solutions can remove barriers to children's communication with healthcare professionals.

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OBJECTIVES

Describe the general and specific objectives, from an applied perspective of translation. Max. 1 page

OBJECTIVE 1. To promote relevant strategies for daily clinical work of gestational diabetes mellitus (GDM) and offspring from conception up to infancy.

OBJECTIVE 2. To demonstrate that primary care implementation of preeclampsia (PE) screening in the first and third trimester of pregnancy decreases the incidence of PE and intrauterine growth restriction (IUGR) in the general population.

OBJECTIVE 3. To establish primary care follow-up for prevention and early-diagnosis of cardiovascular (CV) and kidney risk factors in women that developed preeclampsia (PE) during pregnancy.

OBJECTIVE 4. To study the effects of a wide range of community-level and individual-level environmental risk factors and the effects of lifestyle during pregnancy and its relationship with obstetrical and perinatal outcomes and postnatal health. To implement acceptable and feasible interventions, and to translate the resulting evidence to policy recommendations and prevention strategies in a coordinated hospital and primary care program.

OBJECTIVE 5. To study the identification, outcomes and prevention of prenatal and postnatal exposure to substances of abuse

OBJECTIVE 6. To develop a program program that will be the full integration of ex-preterm infants within the family and the society and the development of all their potential.

OBJECTIVE 7. Identification of patients at risk to prevent or minimize neurodevelopmental disorders by implementing multidisciplinary measures in a hospital and primary care continuity program.

OBJECTIVE 8. To improve the health of mother and child promoting breastfeeding and the use of human milk from birth up to the age of two.

OBJECTIVE 9. To improve health in the community through preventive strategies focus on those factors that influence programming towards obesity and cardiovascular risk in children and adults from the beginning of life.

OBJECTIVE 10. To study the effect of a coordinated hospital and primary care program on the prevention, early detection and monitoring of evolution and sequelae of childhood chronic serious diseases.

OBJECTIVE 11. To identify the mechanisms that improve treatment and follow up of children chronic digestive and renal pathologies and to stablished new protocols for the identification of subjects at risk for the prevention of disease evolution from primary health care units.

OBJECTIVE 12. Employ digital tools to foster a personalised and family-centred approach to maternal and infant primary healthcare, including sensitivity to gender, ethnic and other forms of diversity end users (mothers, fathers and children), as well as the promotion of shared decision-making between them and the healthcare professionals who work with them.

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RESEARCH ACTIVITY PROGRAMME
LIST OF WORK PACKAGES (WP)

OBJECTIVE 1	To promote relevant strategies for daily clinical work of gestational diabetes mellitus (GDM) and c
WP Number	WP description
1	GESTATIONAL DIABETES AND PREVENTION OF METABOLIC RISK FOR MOTHERS AND INFANTS.

OBJECTIVE 2	To demonstrate that primary care implementation of preeclampsia (PE) screening in the first and
WP Number	WP description
2	PREDICTION AND PREVENTION OF PREECLAMPSIA IN A LOW-RISK POPULATION. A BASED PRIMARY CARE STUDY.

OBJECTIVE 3	To establish primary care follow-up for prevention and early-diagnosis of cardiovascular (CV) and
WP Number	WP description
3	PREDICTION AND PREVENTION OFCARDIOVASCULAR AND KIDNEY DIASSESE IN WOMEN WITH PREECLAMPSIA. A BASED PRIMARY CARE STUDY.

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RESEARCH ACTIVITY PROGRAMME
LIST OF WORK PACKAGES (WP)

OBJECTIVE 4	To study the effects of a wide range of community-level and individual-level environmental risk f
WP Number	WP description
4	ENVIRONMENTAL EXPOSURE DURING PREGNANCY AND ITS INFLUENCE ON OBSTETRIC AND PERINATAL OUTCOMES AND ON POSTNATAL HEALTH.

OBJECTIVE 5	To study the identification, outcomes and prevention of prenatal and postnatal exposure to sub
WP Number	WP description
5	PERINATAL AND PAEDIATRIC ENVIRONMENTAL HEALTH: IDENTIFICATION, OUTCOMES AND PREVENTION OF PRENATAL AND POSTNATAL EXPOSURE TO SUBSTANCES OF ABUSE.

OBJECTIVE	6	To develop a program program that will be the full integration of ex-preterm infants within the fa
WP Number		WP description
6		PREMATURITY: LONG-TERM COMPREHENSIVE FOLLOW UP MULTIDISCIPLINARY PROGRAMME INTEGRATING HOSPITAL AND PRIMARY HEALTH CARE SPECIALISTS.

OBJECTIVE	7	Identification of patients at risk to prevent or minimize neurodevelopmental disorders by implem
WP Number		WP description
7		NEURODEVELOPMENTAL IMPAIRMENT AND ASSOCIATED RISK-FACTORS: PRENATAL, NEONATAL AND POSTNATAL MEDICAL AND FAMILY CARE INTERVENTIONS TO IMPROVE OUTCOMES

OBJECTIVE		

OBJECTIVE	8	To improve the health of mother and child promoting breastfeeding and the use of human milk fr
WP Number		WP description
8		BREASTFEEDING AS PROMOTIONAL HEALTH ACTIVITY

OBJECTIVE	9	To improve health in the community through preventive strategies focus on those factors that inf
WP Number		WP description
9		FOETAL-INFANT PROGRAMMING OF OBESITY AND RISK OF ADULT CARDIOVASCULAR MULTIMORBIDITY

OBJECTIVE	10	To study the effect of a coordinated hospital and primary care program on the prevention, early d
WP Number		WP description
10		PREVENTION, CARE AND FOLLOW-UP WITH CONTINUITY OF CARE OF PEDIATRIC PATIENTS WITH SERIOUS PATHOLOGY: COORDINATION AND INTEGRATION OF PRIMARY AND HOSPITAL CARE

OBJECTIVE	11	To identify the mechanisms that improve treatment and follow up of children chronic digestive ar
WP Number		WP description
11		PRIMARY CARE IDENTIFICATION OF CHILDREN AT RISK OF CHRONIC DIGESTIVE AND RENAL PATHOLOGIES AND INTERVENTIONS FOR THE PREVENTION OF DISEASE EVOLUTION.

OBJECTIVE	12	Employ digital tools to foster a personalised and family-centred approach to maternal and infant p
WP Number		WP description
12		PROMOTING A PERSONALISED AND FAMILY-CENTRED MATERNAL AND INFANT PRIMARY HEALTH CARE: IMPROVING SHARED DECISION-MAKING, GENDER-SENSITIVE APPROACHES AND DIGITAL TOOLS

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DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTIVE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	1	Start Date/Start Event	01/01/2022	End Date/End Event	31/12/2024
Description	GESTATIONAL DIABETES AND PREVENTION OF METABOLIC RISK FOR MOTHERS AND INFANTS				
Participant Research Groups (Code)	RG9 (RD21/0012/0002), RG8 (RD21/0012/0012), RG1 (RD21/0012/0001), RG5 (RD21/0012/0003), RG6 (RD21/0012/0017) and RG11 (RD21/0012/0008)				

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

There is an urgent need to find new strategies to prevent obesity development among high-risk populations such as children from gestational diabetes mellitus (GDM) mothers. It is important to screen properly GDM in Primary care Services and paediatricians have to be informed on its diagnosis since these children may develop early metabolic disturbances and impaired growth and development. Improving lifestyle habits pre-pregnancy and among GDM children could represent a promising approach to prevent deteriorated adiposity values.
Accordingly, the main aim of this workpackage includes relevant strategies for daily clinical work of GDM and offspring from conception up to infancy.
The specific objectives of the present work package will be:

• To ascertain the utility of the incorporation of glycated hemoglobin HbA1c and serum glucose at hazard in the first trimester for the diagnosis of GDM in high risk GDM women
• To implement improvements in the diagnosis of GDM in the first trimester in high risk GDM women and follow up of their infants.
• To improve knowledge in dietary habits and vitamin suplements recomendations during pregnancy in GDM and obese pregnant women.
• To improve postpartum care in mothers with GDM.
• To develop cohort follow up studies of growth and dietary habits of infants from GDM mothers and propose of key interventions
• Evaluation of neurodevelopment , sleep and eating disorders according to Omega 3 fatty acid supplementation in 8 years old children from GDM mothers.

Dr. Elvira Larqué from IMIB is an expert on the field of nutrition and metabolic disease in GDM. In order to achieve the related aims, the network will develop the following tasks:

1) Harmonization of interdisciplinary research activity with primary care services at first trimester of pregnancy . Training/ education of study personnel and quality control. Enrollement into clinical trials for incorporation of glycated hemoglobin in the definition and management of gestational diabetes in high risk women at the first trimester. It is important to demonstrate optimal strategies at that first trimester screening in the diagnosis and classification of GDM to improve perinatal outcome. The study has a pragmatic approach aiming to reflect real clinical practice rather than the very tightly controlled circumstances of explanatory trials. Women with previous GDM or high risk probablility of GDM as obese women will be randomly allocated in two groups to detect improvements in maternal and fetal GDM control: positive o'sullivan screening at first trimester, glycated hemoglobin HbA1c≥5.9% or serum Glucose at hazard ≥165-199mg/dl at first trimester. (IMIB, E Llurba, MD Gómez-Roig)

2) Measurements of serum nutritional biomarkers during pregnancy and association with the maternal dietary information recorded from several cohorts from pregnancy to improve the nutrition during pregnancy (G Rodriguez, IMIB, E Llurba, MD Gómez-Roig, O García-Algar). Evaluation also of the impact of nutritional supplements as docosahexaenoic acid (DHA), vitamin E, A or vitamin D in pregnancies with and without complications on their serum levels and perinatal outcomes (IMIB). This would provide solid information in our dietary context for a nutritional educational program for midwifes.

3) Evaluation of dietary habits of GDM mothers postpartum as well as duration of breastfeeding in follow up pregnancy cohorts

(G Rodriguez, E Llurba, MD Gómes-Roig, IMIB). Evaluation of key nutrients in breastmilk from GDM mothers and associations with maternal dietary habits. With the results obtained, guidelines and orientations will be developed for the promotion from primary care of postpartum GDM women, as well as the prevention and treatment of obesity and its comorbidities. These guidelines and orientations will remain as integrated structural material for healthcare activity in primary care.

4) To monitor growth, adiposity and eating behaviour in offspring of GDM in relation to foetal and postnatal programming factors and their dietary and physical activity habits from primary care in follow up studies (MD Mesa, G Rodriguez, E Llurba, MD Gómez-Roig, O García-Algar, IMIB). In individuals classified as being at risk of obese a follow-up and treatment should be considered.

5) Since omega 3 fatty acids as docosahexaenoic acid is lower in cord of GDM babies, the evaluation of neurodevelopment and eating disorders in GDM infants at older ages in follow up cohorts from pregnancy will be performed. (IMIB). A multicenter prospective RCT in children of 8 years old from mother's with GDM during pregnancy will be developed and several psychological tests as well as well as neuroimaging will be applied in order to detect differences in neurodevelopment and sleep recording in these children

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

1) Report on the utility of the incorporation of glycated hemoglobin HbA1c and serum glucose at hazard in the first trimester for the diagnosis of GDM in high risk GDM women (month 36).
2) Educational nutritional program to be used by midwifes to improve nutritional care of pregnant women and high risk of GDM and obese pregnant women (month 12)
3) Report on growth, adiposity and eating behaviour in offspring of GDM (month 30)
4) Educational nutritional program to improve nutritional care, support breastfeeding and dietary intervention in postpartum GDM women (month 24).
5) Report on neurodevelopment , sleep and eating disorders in offspring GDM.(month 30)
6) Guideline for diagnostic and management of women GDM from first trimester of pregnancy in primary care services (month 36).
7) Guidelines and orientations for the promotion from primary care of health in children from GDMs, as well as the prevention and treatment of obesity and its comorbidities (month 36).

MILESTONES´OBJECTIVE

Brief description and date of delivery Max. 2,250 characters

• Harmonization of interdisciplinary research activity with primary care services at first trimester of pregnancy (Month 3)
• Training/education of study personnel and quality control (Month 3)
• Database and biobanck for the storage of data and samples derived from the study (Month 3)
• Serum nutritional biomarkers determinations during during pregnancy (Month 30)
• Breastmilk analysis (Month 30)
• Data analysis: The third year of the project will be mainly dedicated to completing follow-up and data analysis. Conventional statistics will be combined with advanced methods and machine learning, supported by data scientists to identify complex relationships (month 30)
• Dissemination: the last 3 months will be committed to scientific reports, publications and dissemination of results to the scientific community and society (month 36)

RICORS Code	RICORS Leader:
RD21/0012/0001	Elisa Llurba Olivé

DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTVIE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	2	Start Date/Start Event	01/01/2022	End Date/End Event	31/12/2024
Description	PREDICTION AND PREVENTION OF PREECLAMPSIA IN A LOW-RISK POPULATION: A PRIMARY CARE BASED STUDY				
Participant Research Groups (Code)	RG1 (RD21/0012/0001), RG2 (RD21/0012/0015), RG3 (RD21/0012/0014), RG5 (RD21/0012/0003), RG6 (RD21/0012/0017), CA3, RG8 (RD21/0012/0012), RG9 (RD21/0012/0002), RG10 (RD21/0012/0006), C10, C11, and RG15 (RD21/0012/0018)				

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

GENERAL OBJECTIVE
To demonstrate that primary care implementation of preeclampsia (PE) screening in the first and third trimester of pregnancy decreases the incidence of PE and intrauterine growth restriction (IUGR) in the general population.

ACHIEVABLE RESULTS
1. Primary-care implementation of contingent first trimester screening of PE, and early prophylaxis with low-dose aspirin, to reduce the incidence of early-onset PE and neonatal complications in the general population.

2. Reduce the prevalence of term PE and late-onset IUGR by policy of screening for PE in the third trimester of pregnancy by biochemical markers (sFlt1/PlGF ratio) at 35-36 weeks of gestation.

3. Establish updated guidelines and protocols for first and third trimester screening of PE/IUGR in the general population of pregnant women attending primary care.

4. Establish appropriate obstetric management of pregnant women at high risk of late PE.

5. Store biological samples from women at first and third trimester of pregnancy in an ad hoc section of the Biobanks of the participating groups, to be used for future studies on PE and IUGR.
6. Performance of cost-efficiency analyses (maternal and neonatal hospitalization stays and incurred costs).
7. Improve maternal experience in primary care of follow-up of pregnancy, and for participation in decision-making processes regarding pregnancy and delivery.

JUSTIFICATION OF THE STUDY
• Preeclampsia (PE) affects ~5% of pregnancies and remains a leading cause of maternal morbidity and mortality in the world.
• Major challenges in modern obstetrics are identification of women at high-risk for preterm PE early in pregnancy, and interventions to reduce the prevalence of the disease.
• In 2017, a study showed that women who were detected as high-risk in first trimester and treated with aspirin have a 67% reduction preterm PE.
• Since then, first trimester screening has been partially implemented in some tertiary centers in Spain. Two main barriers now need to be solved; first, screening cost, since it includes the biomarker PlGF; and second, not all low-risk women have access to screening in primary care, since it is mainly performed in high-risk settings.
• On the other hand, term PE accounts for 70% of all PE and a large proportion of maternal-fetal morbidity related with this condition. Prediction and prevention of term PE remains unsolved.
• Recent evidence shows that sFlt1/PlGF ratio at 35-37 weeks predicts term PE with 80% detection rate.
• We hypothesize that single-step universal screening for term PE based on sFlt1/PlGF ratio at 35-37 weeks, followed by IOL from 37 weeks onward, would reduce the prevalence of term PE without increasing cesarean section rates or adverse neonatal outcomes.
• If successful, results of these studies will provide evidence to support a simple universal screening strategy to reduce the prevalence of PE, which could be applicable in most healthcare settings, and have enormous implications on perinatal outcomes and public health policies worldwide.

SPECIFIC OBJETIVES AND TASKS
Since the study has hospital and primary care based components, both professional obstetricians and midwifes within the different groups will work closely to achieve relevant results at maternal and neonatal level. In order to achieve the aims of this WP, the network will perform the following tasks under the leadership of Dr Elisa LLurba:
SO.1 Primary-care implementation of contingent first trimester screening of PE, and early prophylaxis with low-dose aspirin, to reduce the incidence of early-onset PE and neonatal complications in the general population.
Tasks: This project has already Ethics approval, and a pilot study was conducted to define the optimal cut-offs for risk and internal validation. This pilot study (Hospital Sant Pau -ASSIR Dreta) achieved a reduction of 62% of preterm PE compared to an historical cohort. Now we are ready for external validation of the method, and for its implementation in a real-world clinical scenario (PI19/00692), in four settings within this network (Aragón, País Vasco, Islas Baleares and Cataluña). We will start running the trial from months 4 to 27: patient recruitment, lab analyses of PlGF and recommendation of aspirin prophylaxis if needed (all centers). 6500 consecutive pregnancies attending first trimester ultrasound of pregnancy in primary care settings will be invited to participate, and upon signed consent form, a combined screening of PE will be performed including maternal characteristics, blood pressure and uterine artery Doppler pulsatility index, with a commercialized software that has already been validated in the Spanish population (PMID: 31972161) (https://www.sbpsoftware.com/es/trisomy-risk-calculator.html). For those with intermediate risk (1/51-1/500), PlGF in maternal blood obtained at first trimester (stored sample) would be determined. The PlGF result will be integrated in the screening tool to reclassify them as either low- or high-risk for development of PE. In patients with an increased risk, low-dose aspirin prophylaxis will be recommended, and specific pregnancy follow-up will be carried out combining primary and reference care surveillance. Finally, variables related to primary and perinatal endpoints will be obtained from months 10 to 30.

SO.2 Reduce prevalence of term PE and late-onset IUGR by policy of screening for PE in the third trimester of pregnancy by biochemical markers (sFlt1/PlGF ratio) at 35-36 weeks of gestation.
Tasks: This is a multicenter open-label randomized controlled trial in non-selected nulliparous pregnant women routinely evaluated at 35-36 weeks' gestation (PI21/00148). Study groups: participants will be randomized to revealed vs concealed maternal angiogenic factor blood values. Interventions: blood sampling at 35-36w to determine sFlt1/PlGF ratio. In the revealed arm, the value will be known by managing clinicians and, if >90th centile, labor induction from 37 weeks onward will be offered. In the concealed arm the value will be unknown. The primary endpoint is development of PE at term. Secondary endpoints: cesarean section rate, neonatal adverse outcomes, maternal morbidity, maternal endothelial function 6-months postpartum, maternal satisfaction and experience, cost-effective analysis. Sample size: 9132 women (4566 per arm) are needed to demonstrate a 50% reduction in term PE (from 1.5%), assuming a 10% loss. Nine primary and hospital care settings will carry out this study: Hospital Clínic, Hospital Sant Joan de Deu, Hospital Sant Pau, Hospital del Mar, Hospital Germans Trias I Pujol (Cataluña), Hospital la Paz (Madrid), Hospital la Fe (Valencia), Hospital Son Llatzer (Mallorca), Hospital de la Reixaca (Murcia), Hospital Clínico de Zaragoza (Aragón). This project has already Ethics approval and a pilot study was conducted to define the optimal cut-offs for sFlt1/PlGF. After the initial setup (database, randomization web, data management plan and statistical analysis plan), we will start running the trial from months 4 to 27: patient recruitment, lab analyses of sFlt1/PlGF and recommendation of labor induction if needed (all centers). Finally, variables related to primary and perinatal endpoints will be obtained from months 10 to 30. Roche Diagnostics International Ltd, Switzerland has committed to support the study by providing consumables required for the sFlt-1/PlGF ratio measures.

SO.3 Establish updated guidelines and protocols for first and third trimester screening of PE/IUGR in the general population of pregnant women attending primary care and Establish appropriate obstetric management of pregnant women at high risk of late PE.
One important objective is to achieve the maximal external validation of results and show applicability of findings in primary and tertiary settings of the Spanish healthcare system. Our experience will reinforce scientific and translational values, and foster publications in the highest impact factor journals. Elisa Llurba and Katty de Paco are authors of the Spanish Society of Obstetrics and Gynecology (SEGO) Guidelines on Hypertension Disorders of Pregnancy (https://sego.es/Guias_de_Asistencia_Practica#), both involved in this work package, therefore assuring updates of the current guidelines and protocols, for their immediate translation into clinical practice.

SO.4 Store biological samples from women at first and third trimester of pregnancy in an ad hoc section of the Biobanks of the participating groups, to be used for future studies on PE and IUGR.
Task: At 9-11.6 and 35.0-36.6 weeks of gestation, 20mL of maternal blood will be drawn for measurement of angiogenic factor serum concentrations using automated platforms that provide reproducible results (Eclecsys, Roche Diagnostics International Ltd, Switzerland). The remaining serum and plasma will be stored at -80ºC for future studies regarding potential biochemical markers for PE in all participating centers of this consortium.

SO.5 Performance of cost-efficiency analyses (maternal and neonatal hospitalization stays and incurred costs).
Cost-benefit and cost-utility analyses will be performed to evaluate the economic impact of the interventions, with a time horizon of 5 years and a broad perspective of the health system. These analyses will be sub-contracted to a dedicated research/university unit specialized in health economics. In brief, costs (capital and recurrent) will be imputed according to standard tariffs in each participating site. For the cost-utility analysis, the cost for QUALY (quality-adjusted live years) gain will be calculated. QUALY of averted PE will be calculated from previous estimations which combine maternal and neonatal health

measures (30571234). A threshold of 25mEur per QUALY gained will be used for cost-effectiveness.

SO.6 Improve maternal experience in primary care of follow-up of pregnancy, and for participation in decision-making processes regarding pregnancy and delivery.
Additionally, questionnaires for maternal experience will be obtained at the time of recruitment and after delivery (all centers) until a determined sample size, which will span the majority of the project's life, till completion. To evaluate maternal feelings and experiences both in cases of low- and high-risk of PE, a specific questionnaire will be designed for focus groups, and validated in a sub-sample of patients from each care setting. This development and validation process will be carried out by the AFIN group, Universidad Autónoma de Barcelona (UAB).

Task distribution
- Elisa Llurba (principal investigator): general coordination of the project, randomization and data collection supervision, supervision of lab analyses, outcomes, statistical analyses, interpretation and dissemination of results.

- Patient recruitment, randomization, follow-up and data collection will be led by Midwifes and Obstetricians at each participating group.
- Cost-effectiveness analyses (research/university unit specialized in health economics).
- Participant surveys design and validation: AFIN group, UAB (led by Dr Diana Marre).

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

After accomplishing these tasks, the following will be obtained:
Reduction in the incidence of preterm PE by 50% (month 30).
Reduction in the incidence of term PE by 50% (month 30).
Reduction of other placental complications of pregnancy, such as IUGR, prematurity and neonatal complications (month 30).
Report on maternal feelings and experiences from these interventions (month 18).
Recommendations of integrated and coordinated Primary Care and Hospital programs for screening of PE and other placental complications of pregnancy will be proposed (month 24).
Report of cost-effectiveness analyses of introduction the two PE screenings in primary-care clinical practice (month 36).
Clinical guidelines for prediction and prevention of PE and other complications of pregnancy such as IUGR, prematurity and neonatal complications (month 36).
Report of evaluation of the Primary Care and Hospital Care Coordinated Program in screening for PE (month 30).
Information material and recommendations for pregnant women relative to PE, prediction and prevention strategies and its consequences (month 36).
Information related to cost per patient to undertake the proposed screening and interventions to reduce PE in the Spanish Health System (month 36).
Biobank of samples from pregnant women at risk for PE for ulterior studies (month 36).

MILESTONES´OBJECTIVE

Brief description and date of delivery Max. 2,250 characters

1. Data management: kick-off and follow-up meetings will take place monthly
2. To set the protocols and SOP for all the procedures and determinations (month 3)
3. To set the framework for sample biobank within the network (month 6)
4. Validation of first trimestre contingent screening of PE to be used in primary care setting in first 400 patients included in the study (moth 12)
5. Validation of diagnostic tools - angiogenic factors near term- that will allow selection of high-risk pregnancies and individualized management (month 12)
6. Analysis of experiences validation survey (month 12)
7. Elaboration of information and recommendation materials for pregnant women, based on women's desires and feelings related to their experiences (month 18)
8. Cost-effectiveness analysis (month 30)
9. Data analysis: The third year of the project will be mainly dedicated to completing follow-up and data analysis. Conventional statistics will be combined with advanced methods and machine learning, supported by data scientists to identify complex relationships (month 30)
10. Dissemination: the last 3 months will be committed to scientific reports, publications and dissemination of results to the scientific community and society (month 36).

RICORS Code	RICORS Leader:
RD21/0012/0001	Elisa Llurba Olivé

DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTVIE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	3	Start Date/Start Event	01/01/2022	End Date/End Event	31/12/2024
Description	PREDICTION AND PREVENTION OF CARDIOVASCULAR AND KIDNEY DISEASES IN WOMEN WITH PREECLAMPSIA. A BASED PRIMARY CARE STUDY				
Participant Research Groups (Code)	RG17 (RD21/0012/0019), RG1 (RD21/0012/0001), RG5 (RD21/0012/0003), RG6 (RD21/0012/0017), RG15 (RD21/0012/0018), CA5, CA6, RG18 (RD21/0012/0024) and RG9 (RD21/0012/0002)				

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

GENERAL OBJECTIVE
To establish primary care follow-up for prevention and early-diagnosis of cardiovascular (CV) and kidney risk factors in women that developed preeclampsia (PE) during pregnancy.

JUSTIFICATION OF THE STUDY
• CV disease is the leading cause of death in women.
• PE affects ~5% of pregnancies. It is a pregnancy-related hypertensive disorder driven by an anti-angiogenic environment that can also be enhanced by potentially modifiable CV risk factors such as presence of toxins, lipid alterations or coagulation disorders. Women that experience PE during pregnancy have 2 to 4 times higher risk of developing CV disease.
• We postulate that maternal exposure to anti-angiogenic factors (sFlt1) during pregnancy impairs CV adaptation, mainly by affecting endothelial function. These effects are at least partially mediated by placental dysfunction, and in women with PE, exposure to high levels of anti-angiogenic factors impairs heart, renal and endothelial functions, accounting for increased risk of CV disease later in life.
• We hypothesize that postpartum monitoring in women with history of PE, and implementation of life-style recommendations, can improve their health, reducing CV risk and the burden of the disease.
• Maternal-fetal, CV and Hypertension Societies recommend follow-up for CV disease, but not specific guidelines have been published to determine that. Implementation of follow-up protocols for primary care surveillance of these women may aid with early recognition of CV risk factors and prompt treatment.
• There is urgent need for education about this CV risk in primary health care workers and women.
• If successful, these studies will provide evidence to support a simple universal follow-up strategy, reducing the prevalence of CV and kidney risk factors in women with history of PE, applicable in most healthcare settings, and have enormous implications on public health policies worldwide.

SPECIFIC OBJETIVES AND TASKS
Since the study has a hospital and primary care-based component, family care doctors, nephrologists, cardiologists, obstetricians and midwifes within the different groups will work closely to achieve the objectives of this WP. The leader of the work-package will supervise tasks regarding intellectual and clinical work, that will be reflected in guidelines, protocols, abstracts and peer-reviewed papers. In order to achieve the aims of this WP, the network will perform the following tasks under the leadership of Dr Patricia Fernández-Llama:
SO 1: Evaluation of placental, metabolic, renal and CV biomarkers during pregnancy in women at risk of PE and in women who develop PE and at 12 months after delivery.
Tasks: This project has already Ethics approvals and pilot studies are being conducted in five settings within the consortium with funding granted or submitted at ISCIII (AES 2021):
1. Sant Pau Hospital-ASSIR Dreta (PI19/00702_PI E. Llurba)
2. Hospital 12 de Octubre (PI19/01579_PI A. Galindo).
3. Fundació Puigvert (PI21/01998_PI P. Fernández-Llama)
4. Hospital Clínic-H Sant Joan de Déu (PI21/00148_PI E. Gratacós)
5. Virgen de la Arrixaca, Murcia
Type of study: prospective cohort with nested case-control from these participating centers.
Inclusion criteria: 1) High-risk for PE according to first or third trimester screening (maternal risk factors, blood pressure, PAPP-A, mean pulsatility index of uterine arteries (UtA) (n=280). 2) Women with clinical signs and symptoms of PE (N=120). 3) 100 low-risk pregnant women.
INTERVENTIONS: During first and third trimester of pregnancy, upon diagnosis of PE and 12 months after delivery.

Epidemiological data.
Anthropometric measures
24-hour blood pressure monitoring: provides key parameters of vascular and cardiac function and CV risk: brachial and aortic blood pressure, cardiac load, peripheral and aortic pulse waveform, and arterial stiffness measurement by pulse wave velocity (Mobil-O-Graph PWV□, Germany).
cIMT (carotid intima-media thickness): includes a primary and transverse longitudinal evaluation of the common carotid artery, its bifurcation and internal carotid artery. The measurements will be made by peak R-wave in a site without atherosclerotic plaques.
Echocardiography: performed by a cardiologist specialized in cardiac imaging according to usual standard protocol. High-resolution images will be acquired and post-processed with dedicated software for speckle tracking analysis, 2D echocardiography parameters, tissue Doppler and speckle tracking software (With Automated Cardiac Motion Quantification aCMQ-STRAIN by Philips).
2D and 3D echocardiography assessment of carotid and femoral arteries: for the identification, quantification and characterization of atheroma plaques.
Biochemical markers in maternal blood and urine: angiogenic factors and cardiac function biomarkers: sFIT-1, PlGF, high-sensitivity Troponin and NT-proBNP will be measured using automated electrochemiluminescence immunoassays on the Roche Cobas platform (Roche Diagnostics GmbH, Mannheim, Germany). Copeptin will be measured in a Kryptor instruments by an immunoluminometric assay using two polyclonal antibodies directed to the 132–164 aminoacids of proAVP (BRAHMS, Thermo-Fischer, Germany). Mass spectrometry analysis will be performed by a high-quality equipment generation (Q-Exactive® Focus, Thermo Fisher Scientific®). Urinary albumin and protein ratio by standard procedure.

PREDICTIVE VARIABLES
- Main predictive variables: study group, sFlt-1/PlGF ratio.
- Secondary: uterine Doppler, arterial stiffness, maternal blood pressure, maternal toxin serum levels, lipids and coagulation factors, ambulatory mean arterial pressure, biomarkers of oxidative status.

MAIN OUTCOME MEASURES
- Cardiac, vascular and renal dysfunction/remodeling in the first and third trimesters of pregnancy and 12 months after delivery defined as:
1. Abnormal cardiac performance in echocardiographic ultrasound assessment or/and
2. Abnormal biochemical cardiac markers and/or
3. Abnormal toxins serum levels, lipids and coagulation factors and/or
4. Abnormal hypertensive phenotype in ambulatory blood pressure monitoring and/or
5. Abnormal carotid/femoral intima media thickness and/or
6. Abnormal echocardiography
7. Abnormal albumin/creatinine or protein/creatinine in urine and/or
8. Abnormal oxidative status
9. Abnormal subpopulation of extracellular vesicles in urine.
-Cardiac, renal and metabolic status at 12 m after delivery and its correlation with cardiac, renal and PE risk variables obtained during pregnancy.

SO 2: Predictive algorithm to create an score for CV and renal risks after pregnancy.

1. Prediction combined model including biochemical and biophysical markers of CV, renal and placental dysfunction for development of PE.
2. Prediction combined model including biochemical and biophysical markers of CV, renal and placental dysfunction for development of CV risk after delivery (12 months).
3. Prediction model using computational machine learning techniques to assess CV risk of women 2 – 12 years after suffering early PE.

SO 3: Primary-care implementation of a validated CV score for women that developed PE during pregnancy, for early detection of CV and renal risk factors.

A validated tool developed for the Spanish population (IBERLIFERISK) will be used to estimate CV risk at short, mid and long-term for lethal and non-lethal CV events in women with PE, and these estimations will be compared with women without PE. Relevant information will be obtained to assess whether female-specific conditions such as PE improve CV risk classification. This tool has been developed from results of project PI17/01031 “External validity of a lifelong CV risk score”, PI Carles Brotons from primary care attention EAP SARDENYA, and member of our proposal.
Sample size would include 120 patients with previous PE and 100 controls from those included in objectives 1-4.
S0 4: To publish guidelines and protocols for recognition and prevention of CV and renal diseases in women after pregnancy complications, managed in primary care.

Our experience will reinforce scientific and translational values, and foster publications in the highest impact factor journals. Elisa Llurba, Carles Brotons, Patricia Fernandez-Llama, Nadia Ayasreh, Anna Oliveras and Alex de la Sierra and Lidia Bos are involved in the Spanish Societies of Obstetrics and Gynecology (SEGO), Primary care (https://www.semFYC.es), Nephrology (SEN), and Hypertension (https://seh-lelha.org) and Cardiology (https://secardiologia.es) respectively, therefore assuring updates of the current guidelines and protocols, for their immediate translation into clinical practice.
SO 5: Creation of a Biobank
At 9-11.6 weeks of pregnancy, during PE development and one-year after index pregnancy, 20mL of maternal blood will be taken for objectives 1-4. The remaining serum and plasma will be stored at -80ºC for future studies regarding potential biochemical markers for PE in all participating centers of this consortium.
SO 6: To create and validated an app for surveillance of lifestyle interventions for prevention of CV disease in women with PE during pregnancy.
A specific app for mothers at risk for CV and kidney disease will be designed with information provided from the results of this study, in combination with previously available solutions, improve exercise and diet, together with at-home surveillance of blood pressure and maternal wellbeing. Tailored information regarding diet and exercise in this specific period of time would be included. Moreover, young and lactating mothers’ point-of-views and needs would be taken into account.
Validation of the app would be assessed by:
• Health-Promoting Lifestyle Profile questionnaire: evaluates whether the subjective perception of patients regarding their lifestyle has changed and consists of 52 items (https://deepblue.lib.umich.edu/handle/2027.42/85349).
• Quality of life: participants will complete the World Health Organization Quality of Life—BREF (WHOQOL-BREF), considered a reliable, generic multidimensional quality of life measure and consists of 26 items (https://www.who.int/toolkits/whoqol).
Sample size: would include 100 patients from PE patients that deliver during the study in all the participating centers.

Task distribution
- P. Fernández-Llama (PI): general coordination of the project, data collection supervision, supervision of lab analyses, outcomes.
- Analysis, interpretation and dissemination of results performed by the entire investigation group.
- Patient recruitment, randomization, follow-up and data collection will be led by Midwifes and Obstetricians at each participating group.
- Participant surveys design and validation: AFIN group, UAB (led by Dr Diana Marre).
- App design would be sub-contracted to Barcelona Health hub (https://barcelonahealthhub.com).

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

After reaching these tasks, the following will be obtained:
Deliverable 1 (related to SO.1)
Publication reporting the relation between CV variables during pregnancy and development of PE (month 24).
Publication reporting multivariate analyses of CV and kidney variables during pregnancy and risk of impaired cardiac and renal function 12 months after delivery (month 24).
Publication reporting multivariable analyses of differences in serum metabolites between normal pregnancies and those complicated with late-onset PE (month 24).

Deliverable 2 (related to SO.2)

Publication on a CV score for women that developed PE during pregnancy for early detection of CV risk factors (month 30).
Deliverable 3 (related to SO.3)
Publication on results of the Analysis of Health-Promoting Lifestyle Profile and WHOQOL-BREF questionnaire in the study groups after app validation (month 30).

Deliverable 4 (related to SO.4)
Clinical guidelines and recommendations for prediction and prevention of CV disease in women that developed PE (month 36).
Recommendations of integrated and coordinated Primary Care and hospital program for CV and renal risk factors in women with PE during pregnancy (month 36).
Infographics and short videos on recommendations for young women relative to PE and CV disease, prediction and prevention strategies and its consequences (month 36).

Deliverable 5 (related to SO.5)
Biobank of samples from pregnant women at risk for PE for further studies (month 36).

Deliverable 6 (related to SO.6)
App for implementation of life-style interventions to improve quality of life after PE in young mothers (month 36).

MILESTONES´OBJECTIVE

Brief description and date of delivery — Max. 2,250 characters

1. Data management: kick-off and follow-up meetings will take place monthly
2. To set the protocols and SOP for all the procedures and determinations (month 3)-
3. To set a sample biobank within the network (month 6)
4. To analyze angiogenic factors and CV disease variables in subsequent development of CV complications in women after an episode of placental insufficiency (month 12)
5. To establish biophysical and biochemical biomarkers for CV risk after pregnancy complicated with PE (month 12)
6. Cardiac dysfunction and metabolic status at 12 months after delivery and its correlation with cardiac and PE risk variables obtained during pregnancy (month 24)
7. A CV score for women that developed PE during pregnancy for early detection of CV risk factors (month 24)
8. Analysis of Health-Promoting Lifestyle Profile and WHOQOL-BREF questionnaire in the study groups (month 24)
9. Development of CV risk app (month 24)
10. Validation of app (month 30)
11. Data analysis: The third year of the project will be mainly dedicated to completing follow-up and data analysis. Conventional statistics will be combined with advanced methods and machine learning, supported by data scientists to identify complex relationships (month 30)
12. Dissemination: the last 3 months will be committed to scientific reports, publications and dissemination of results to the scientific community and society (month 36)

RICORS Code	RICORS Leader:

DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTVIE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	4	Start Date/Start Event	01/01/2022	End Date/End Event	31/12/2024
Description	ENVIRONMENTAL EXPOSURE DURING PREGNANCY AND ITS INFLUENCE ON OBSTETRIC AND PERINATAL OUTCOMES AND ON POSTNATAL HEALT				

Participant Research Groups (Code)	RG5 (RD21/0012/0003), RG6 (RD21/0012/0017), RG1 (RD21/0012/0001), RG18 (RD21/0012/0024), RG8 (RD21/0012/0012), RG9 (RD21/0012/0002), RG3 (RD21/0012/0014) and RG14 (RD21/0012/0016)

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

GENERAL OBJECTIVE
To study the effects of a wide range of community-level and individual-level environmental risk factors and the effects of lifestyle during pregnancy and its relationship with obstetrical and perinatal outcomes and postnatal health. To implement acceptable and feasible interventions, and to translate the resulting evidence to policy recommendations and prevention strategies in a coordinated hospital and primary care program.

OBJETIVES AND TASKS
1.- To study the effects of a wide range of community-level and individual-level environmental risk factors (air pollution, noise, green spaces, chemicals and endocrine disruptors) during pregnancy on fetal growth, hypertensive disorders, prematurity, prenatal neurodevelopment, perinatal morbidity and postnatal health: infant neurodevelopment, pediatric obesity and cardiometabolic disorders.
Tasks
1.1 To follow up a population-based cohort of 1200 healthy pregnant women with singleton pregnancy. Participants were recruited at their first prenatal visit (occurring between weeks 6-10 of gestation) at the ASSIR (Primary Care Center), Hospital Sant Joan de Déu and Hospital Sant Pau from Barcelona.
1.2 Characterizing placental function from this cohort. We will conduct Doppler ultrasound measurements of (i) uterine artery pulsatility index (PI), (ii) umbilical artery PI, (iii) middle cerebral artery PI, and (iv) cerebroplacental ratio at weeks 33-36 of gestation.
1.3 Characterizing fetal growth from this cohort: including (i) birth weight, (ii) low birth weight (LBW, birth weight<2500gr), and (iii) fetal growth restriction defined as birth weight below the 10th percentile for the gestational age and sex according to reference tables for the Spanish population (Figueras et al. 2008).
1.4 Assessment of exposure to air: the main aim of this task is to robustly estimate maternal exposure as well as inhaled dose of traffic-related air pollutants in the main microenvironments for pregnant women (i.e. home, workplace, and the commuting route between these two). Due to their relevance in terms of exposure as well as their potential impact on fetal growth, we will assess exposure to NO2, PM2.5, PM2.5 light absorption (as a marker of tailpipe emissions), and PM2.5 Cu, Fe, and Zn (as markers of non-tailpipe emissions).
1.5 Characterization of noise exposure: the aim of this task is to (i) measure ambient noise levels and peaks (attributable to traffic) at home of each participant, (ii) model ambient noise levels at home, workplace, and commuting route, and (iii) characterize noise annoyance, sensitivity, and protections against noise among participants.
1.6 Greenness: We will assess greenness by means of Normalized Difference Vegetation Index (NDVI) (Weier and Herring 2000) derived from aerial images at 0.55 m × 0.55 m resolution. To our knowledge this is the finest resolution NDVI map ever used in epidemiological studies which till now have mainly relied on data obtained by MODIS (250m × 250m resolution), Landsat (30 m × 30 m resolution) and Sentinel (20m × 20m resolution) satellites. NDVI is an indicator of greenness based on land surface reflectance of visible (red) and near-infrared parts of spectrum (Weier and Herring 2000). It ranges between −1 and 1 with higher numbers indicating more greenness (i.e. photosynthetic activity). The aerial images will be captured and processed by the Cartographic and Geology Institute of Catalonia (ICGC) using Leica DMC III Airborne Digital Camera.
1.7 Characterization of exposure to chemicals and endocrine disruptors: cotinine, nicotine, ethyl glucuronide (EtG) levels in maternal hair and phosphatidyl ethanol (Peth) in umbilical cord blood. Per-and polyfluoroalkyl substances (PFASs), metals and elements, phthalate metabolites, phenols, organophsphate pesticides and other pesticides, glycol ethers, polycyclic aromatic hydrocarbon (PAHs), and persistent organic pollutants in urine maternal samples.
1.8 Creation of a Biobank of maternal and fetal samples: maternal blood, maternal hair, maternal urine, umbilical cord blood and placenta.
1.9 To characterize, according to the exposure to air pollution, noise, green spaces and chemicals neurodevelopment by prenatal advanced neurosonography done at 32-34 weeks of gestation.
1.10 To evaluate, according to the exposure to air pollution, noise, green spaces and chemicals, the prevalence of adverse perinatal outcome, defined as any of the following outcomes: (i) Preterm birth: delivery <37 weeks' gestation; (ii) preeclampsia: systolic blood pressure (SBP) ≥ 140mmHg or diastolic blood pressure (DBP) ≥ 90mmHg at least 4 h apart after 20 weeks of gestation and proteinuria of ≥300 mg in 24 h; (iii) perinatal mortality: fetal or neonatal mortality (within 28 days of life); (iv) severe fetal growth restriction: birthweight <3rd centile; (v) metabolic acidosis; (vi) major neonatal morbidity.
1.11 To evaluate, according to the exposure to air pollution, noise, green spaces and chemicals, newborn neurodevelopment by several postnatal tests at different ages; i) Brazelton test at 1-3 months of age; ii) Age and Stages Questionnaires at 12 months of age; iii) Bayley-III score at two years of postnatal age for the evaluation of several items: cognitive, language, motor, socio-emotional.
1.12 To characterize, according to the exposure to air pollution, noise, green spaces and chemicals, the cardiovascular remodelling prenatally by advance echocardiography done at 33-34 weeks of gestation, postnatally by the evaluation of blood

pressure and heart rate at two years of postnatal age.
1.13 To evaluate, according to the exposure to air pollution, noise, green spaces and chemicals, pediatric obesity and cardiometabolic disorders: insulin resistance, hypertension, dyslipidemia and diabetes.
1.14 To evaluate in an animal model the effect of plasticizers in brain neurodevelopment, by using an in vitro neurosphere model obtained from neural progenitor cells from different animal models (rabbit and sheep model). The effect of the plasticizers in brain neurogenesis will be measured, including: proliferation, migration, differentiation into neurons, olygodendrocytes and astrocytes.

Lead partners
This objective will be led by Hospital Sant Joan de Déu Group.
Investigation groups of ASSIR (Primary Care Centers) and Hospital Sant Pau Barcelona, Hospital Clínic Barcelona, Hospital Clinic Zaragoza, Hospital 12 Octubre Madrid, Hospital Virgen Arrixaca Murcia and Hospital La Paz Madrid will participate in the recruitment at first trimester and follow up the patients during pregnancy and during postnatal follow up of the newborns and infants.
2.- To study the effects of maternal lifestyle (diet, stress, exercise, lifestyle habits, toxics intake) during pregnancy on fetal growth, hypertensive disorders, prematurity, prenatal neurodevelopment, perinatal morbidity and postnatal health: infant neurodevelopment, pediatric obesity and cardiometabolic disorders.
Tasks
2.1 To follow up a cohort of a randomized controlled trial (IMPACT BCN: Improving Mothers for a better PrenAtal Care Trial BarCeloNa) of 1221 singleton pregnancies. Women were randomized following a 1:1:1 ratio to one of three arms of intervention: i) Mediterranean diet; ii) Mindfulness Based Stress Reduction program; iii) usual care without any intervention.
2.2 To evaluate, in each of the three study arms, the maternal diet pattern, with a face-to-face interview with a dietitian at enrolment (19-23 weeks) and at the end of the intervention (34-36 weeks): i) a 151-item food-frequency questionnaire; ii) a 17-item dietary assessment score to measure the adherence to the Mediterranean diet.
2.3 To evaluate, in each of the three study arms, the maternal stress with several questionnaires assessed at enrolment (19-23 weeks) and at the end of the intervention (34-36 weeks): i) State-trait Anxiety Inventory-STAI; ii) Perceived Stress Scale-PSS; iii) WHO Five Well Being Index; iv) Five Facet Mindfulness Questionnaire-FFMQ; v) Pittsburgh Sleep Quality Index-PSQI).
2.4 To evaluate, in each of the three study arms, the prevalence of adverse perinatal outcome, defined as any of the following outcomes: (i) Preterm birth: delivery <37 weeks' gestation; (ii) fetal growth restriction defined as newborns with a birthweight below the 10th centile according to the Spanish population (Figueras et al. 2008); (iiI) preeclampsia; (iv) Perinatal mortality: fetal or neonatal mortality (within 28 days of life); (v) Severe fetal growth restriction: birthweight <3rd centile; (vi) Metabolic acidosis; (vii) Major neonatal morbidity.
2.5 To characterize, in each of the three study arms, neurodevelopment by prenatal advanced neurosonography done at 32-34 weeks of gestation; additionally, newborn neurodevelopment will be evaluated also postnatally, by several postnatal tests at different ages; i) Brazelton test at 1-3 months of age; ii) Age and Stages Questionnaires at 12 months of age; iii) Bayley-III score at two years of postnatal age for the evaluation of several items: cognitive, language, motor, socio-emotional.
2.6 To characterize, in the three study arms, the cardiovascular remodelling prenatally by advance echocardiography done at 33-34 weeks of gestation, postnatally by the evaluation of blood pressure and heart rate at two years of postnatal age.

Lead partners
This objective will be led by Hospital Sant Joan de Déu Group.
Investigation groups of Hospital Sant Pau Barcelona, Hospital Clínic Barcelona, Hospital Clinic Zaragoza, Hospital 12 Octubre Madrid, Hospital Virgen Arrixaca Murcia and Hospital La Paz Madrid will participate in the recruitment and and follow up the patients during pregnancy and during postnatal follow up of newborns and infants.

3.- To implement acceptable and feasible interventions, and to translate the resulting evidence to policy recommendations and prevention strategies in a coordinated hospital and primary care program.
Tasks
3.1 Dissemination of finding to the scientific community: the findings will be disseminated through scientific articles, presentations in national and international scientific conferences and workshops, and discussions in relevant scientific societies, associations, and platforms.
3.2 Knowledge transfer to policymakers/stakeholders/general public: the dissemination plan also includes the involvement of patients, so that they are aware of the results. Disseminate the results in different forums, such as patient-oriented health guides.
3.3 Training for health professionals on maternal exposure and child health: education, advocacy and research are the critical unifying themes for all work. Identifying medical training opportunities to incorporate environmental health into all levels of training.
3.4 Training and creation of informative material for pregnant women on exposure, maternal and child health.
3.5 Participation in National and International Scientific Societies. Collaborating with the World Health Organization and FIGO (International Federation of Gynecology and Obstetrics) committees so that environmental health is considered in each area.

Lead partners
This objective will be led by ASSIR (Primary Care Centers).

Investigation groups Hosp Sant Pau Barcelona, Hosp Clínic Barcelona, Hosp Clinic Zaragoza, Hosp 12 Octubre Madrid, Hosp Virgen Arrixaca Murcia and Hosp La Paz Madrid will participate also in the dissemination of the findings and knowledge transfer to general public and in the training of health provider cares.

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

1. Report of the maternal exposure to air pollution, noise and greenness surrounding participants' homes (month 24)
2. Report of maternal exposure to chemicals and endocrine disruptors (month 24). Report of the effect of air pollution, noise, green spaces, chemicals and endocrine disruptors on the prevalence of fetal growth, hypertensive disorders, prematurity, prenatal neurodevelopment (month 24).
3. Report of the effect of air pollution, noise, green spaces, chemicals and endocrine disruptors on the prevalence adverse perinatal outcomes (month 24).
4. Report of the effect of air pollution, noise, green spaces, chemicals and endocrine disruptors on the postnatal health: infant neurodevelopment, pediatric obesity and cardiometabolic disorders (month 24).
5. Report of the effect of different maternal life-style strategies, such as Mediterranean Diet and a Mindfulness Based Stress Reduction program, on the prevalence of fetal growth restriction and adverse perinatal outcome (hypertensive disorders, prematurity, perinatal mortality and morbidity) (month 24).
6. Report of the effect of the Mediterranean Diet and a Mindfulness Based Stress Reduction program on prenatal and postnatal neurodevelopment, and on cardiovascular assessment during prenatal and postnatal life (month 24).
7. To store biological samples from women, cord blood and placenta in Biobanks of the participating groups to be used for future studies on environmental exposure during pregnancy (month 36).
8. Clinical guidelines and protocols for early detection, prevention and follow-up of maternal exposure to community-level and individual-level environmental risk factors and lifestyle risk factors from the prenatal period (month 36).
9. Report of the results of education activities of health care education (month 36).
10. Recommendations of education activities of health care education in high risk children and families (month 36).
11. Report of prevention strategies in a coordinated primary care program and hospital on the effects of environmental risk factors and lifestyle to reduce adverse perinatal outcomes, poor infant neurodevelopment, obesity and cardiometabolic syndrome in infants (month 36).

MILESTONES´OBJECTIVE

Brief description and date of delivery Max. 2,250 characters

In summary, at the end of the study this WP will provide:
• Data management: kick-off and follow-up meetings will take place monthly
• To set the protocols and SOP for all the procedures and determinations (month 3)
• To set a data base and a sample biobank within the network (month 6)
• Prospective follow-up and integration data of the maternal exposure to community-level and individual-level environmental risk factors and lifestyle risk factors from the prenatal period to early childhood (month 36).
• Biobank of samples from pregnant women, cord blood and placenta for ulterior studies on environmental exposure during pregnancy (month 36).
• Clinical guidelines and recommendations for the early detection and prevention of community-level and individual-level environmental risk factors during pregnancy (month 36)

RICORS Code	RICORS Leader:

DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTVIE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	5	Start Date/Start Event	01/01/2022	End Date/End Event	13/12/2024

Description	PERINATAL AND PAEDIATRIC ENVIRONMENTAL HEALTH: IDENTIFICATION, OUTCOMES AND PREVENTION OF PRENATAL AND POSTNATAL EXPOSURE TO SUBSTANCES OF ABUSE.
Participant Research Groups (Code)	RG6 (RD21/0012/0017), RG5 (RD21/0012/0003), RG2 (RD21/0012/0015), RG4 (RD21/0012/0009), RG3 (RD21/0012/0014), RG9 (RD21/0012/0002), RG1 (D21/0012/0001), RG19 (RD21/0012/0023) and RG15 (RD21/0012/0018)

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

Main objective:
To study the identification, outcomes and prevention of prenatal and postnatal exposure to substances of abuse
Specific objectives:
1. To study the prevalence of consumption of different substances of abuse in a vulnerable population: pregnant women, newborns and infants
2. To design specific preventive interventions about exposure to substances of abuse from conception to adolescence
3. To design follow up strategies and guidelines for children and adolescents prenatally and postnatally exposed to substances of abuse
4. To design and to implement a proposal of maternal and child environmental health program to be applied in Primary Care settings

Workpackage Definition
This Work Package has a broad health care profile, including absolutely Primary Care health workers and also hospital care professionals, with the aim of studying an environmental determinant of health (exposure to substances of abuse) in a very susceptible population: pregnant women, newborns, infants, children and adolescents, and some specific risk groups. Primary Care-hospital cooperation is an ongoing project in this field because the research group (several of the researchers) are cofounders and members of the Board of 2 academic and professional societies: the workgroup about Pediatric Environmental Health of the Societat Catalana de Pediatria and the Environmental Health Committee of the Asociación Española de Pediatría. E-health resources are an important component of all these tasks.

Objectives
Objective 1. To study the prevalence of consumption of different substances of abuse in a vulnerable population: pregnant women, newborns and infants
Tasks:
• To determine the prevalence of exposure to substances of abuse (i.e., alcohol, cannabis, other drugs of abuse) during pregnancy in different biological matrices (neonatal meconium, maternal hair, breast milk): (1) a cohort of pregnant women recruited in a collaborative study in Sevilla (in cooperation with the Psychology Department of the University of Huelva (Prof. Ramon Mendoza)); (2) a cohort of pregnant women consumers of cannabis in Barcelona (in cooperation with the Health Department of the Generalitat de Catalunya).
• To design different resources for this aim: (1) a webinar about consumption of substances of abuse during pregnancy and breastfeeding (in cooperation with the Antropology Department of the University of Barcelona); (2) guideline about deleterious effects of environmental contaminants and consumption of substances of abuse during pregnancy.

Objective 2. To design specific preventive interventions about exposure to substances of abuse from conception to adolescence
Tasks:
• To design and develop preventive strategies about prenatal and postnatal exposures to substances of abuse: (1) to create an inventory about good and best practices to reduce alcohol-related harm among women of childbearing age and pregnant women in particular; (2) to develop recommendations on alcohol exposed pregnancies prevention; (3) to develop a specific preventive program about prevention of consumption of substances of abuse during pregnancy (all of the three in cooperation with the Health Department of the Generalitat de Catalunya)
• To design and develop intervention strategies about prenatal and postnatal exposure to substances of abuse: (1) to validate an intervention strategy based on a motivational intervention in order to avoid or to reduce alcohol consumption during pregnancy; (2) to create specific guidelines about diagnosis and treatment of the Fetal Alcohol Spectrum Disorder (a diagnostic App (VisualFASD) based on artificial intelligence and a therapeutic suite based on virtual reality (Mental XR), both of the them in the framework of the start-up of the group: Psicoterapia VR)

Objective 3. To design follow up strategies and guidelines for children and adolescents prenatally and postnatally exposed to substances of abuse
Tasks:

• To design follow up strategies for children prenatally exposed to substances of abuse: (1) to design a public health algorithm for diagnosis and follow up of children with FASD (native or adopted from East Europe countries) in order to be included in the program of follow up of healthy children in primary Care settings (in cooperation with the Health Department of the Generalitat de Catalunya); (2) to write specific guidelines for professionals and families about FASD (in cooperation with VisualTEAF, an association of families of affected children)
• To develop and participate in the strategic program about mental health problems of high complexity in cooperation with the Health Department of the Generalitat de Catalunya (Programa d'abordatge integral dels casos de salut mental d'elevada complexitat (PAICSAMAEC))

Objective 4. To design and to implement a proposal of maternal and child environmental health program to be applied in Primary Care settings
Tasks:
• To design a model of maternal and child environmental health program in cooperation with the 2 collaborative societies: Societat Catalana de Pediatria and Asociación Española de Peditatría
• To design and to implement a model of intervention unit (pehsu: pediatric environmental health speciality unit) about maternal and child environmental health in Primary Health settings

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

Deliverable 1 (related to objective 1)
Data about to the prevalence of exposure to substances of abuse during pregnancy in 2 cohorts:
(D1a) Sevilla (alcohol) – month 12m
(D1b) Barcelona (cannabis) – month 24
Deliverable 2 (related to objective 1)
Files of the resources for this aim:
(D2a) webinar about consumption of substances of abuse during pregnancy and breastfeeding – month 12
(D2b) guidelines about deleterious effects of environmental contaminants and consumption of substances of abuse during pregnancy – month 24

Deliverable 3 (related to objective 2)
Files of the preventive strategies about prenatal and postnatal exposures to substances of abuse:
(D3a) inventory about good and best practices to reduce alcohol-related harm among women – month 12
(D3b) recommendations on alcohol exposed pregnancy prevention – month 24
(D3c) a specific preventive program about prevention of consumption of substances of abuse during pregnancy – month 36
Deliverable 4 (related to objective 2)
Data and files of the intervention strategies about prenatal and postnatal exposure to substances of abuse:
(D4a) validated intervention strategy based on motivational intervention – month 30
(D4b) specific tools about diagnosis and treatment of FASD – month 24

Deliverable 5 (related to objective 3)
Files on follow up strategies for children prenatally exposed to substances of abuse:
(D5a) algorithm for diagnosis and follow up of children with FASD – month 18
(D5b) specific guidelines for professionals and families about FASD – month 12

Deliverable 6 (related to objective 3)
(D6) Data about the development of program about mental health problems of high complexity – month 30
Deliverable 7 (related to objective 4)
(D7) A file of a model of maternal and child environmental health program – month 36

Deliverable 8 (related to objective 4)
(D8) A file of a model of intervention unit about maternal and child environmental health – month 36

MILESTONES´OBJECTIVE

Brief description and date of delivery Max. 2,250 characters

This objective includes all the aspects of the identification, outcomes and prevention of prenatal and postnatal exposure to substances of abuse in the framework of a maternal and child environmental health program to be applied in Primary Care settings. It also provides strategies and guidelines for preventive, intervention and follow up studies related to exposure to substances of abuse from the conception until the adolescence.

1. Data about to the prevalence of exposure to substances of abuse during pregnancy in 2 cohorts will be finished by 24 months
2. Webinar about environmental contaminants and consumption of substances of abuse during pregnancy will be finished by 24 months
3. Guidelines about environmental contaminants and consumption of substances of abuse during pregnancy will be finished by 24 months
4. Preventive strategies about prenatal and postnatal exposures to substances of abuse will be developed by 36 months
5. Intervention strategies about prenatal and postnatal exposure to substances of abuse will be developed by 30 months
6. Strategies for children prenatally exposed to substances of abuse (children with FASD) will be finished by 18 months.
7. The development of program about mental health problems of high complexity will be done by 30 months
8. A model of maternal and child environmental health program and a model of intervention unit about maternal and child environmental health will be developed by 36 months

RICORS Code	RICORS Leader:

DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTVIE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	6	Start Date/Start Event	01/01/2022	End Date/End Event	31/12/2024
Description	PREMATURITY: LONG-TERM COMPREHENSIVE FOLLOW UP MULTIDISCIPLINARY PROGRAMME INTEGRATING HOSPITAL AND PRIMARY HEALTH CARE SPECIALISTS.				
Participant Research Groups (Code)	RG2 (RD21/0012/0015), RG10 (RD21/0012/0006), RG9 (RD21/0012/0002), RG11 (RD21/0012/0008), RG5, (RD21/0012/0003), RG4 (RD21/0012/0009), RG8 (RD21/0012/0012), RG3 (RD21/0012/0014), RG1 (RD21/0012/0001) and RG14 (RD21/0012/0016)				

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

Objective 1. To create an online training program for primary care pediatricians and pediatric nurses that includes:
1) Use of Ages & Stages Questionnaires® screening, 3rd edition (ASQ-3®) as recommended by the National Follow Up Program for Late Preterm and downloadable from the page www.proyectoacuna.es .
2) Training in handling of the Clinical Electronic Registry Data Base for Late Preterm.
3) Discuss a Follow Up Flow Diagram.
Duration 3 months (1.1.2022 – 30.3.2022).
Objective 2. To design an ad hoc electronic data registry to store all the clinical and analytical data related to the patients' evolving during the first 24 months after birth that will allow uploading all the data to the R statistical program for analysis.
Duration 3 months (1.1.2022 – 30.3.2022)

Objective 3. To initiate the Follow Up Program strategy for Late Preterm Infants (>34 to 36+6 weeks of gestation) in participating Health Areas of different regions of Spain (Valencia, Madrid, Murcia, Bilbao, Barcelona, Granada, Cantabria). The study includes health care professionals of Maternity and Neonatal Wards and the corresponding Primary Health Areas. The program aims to early detect neurodevelopmental and sensorial deficits through the statistical analysis of health and developmental data registered in ad hoc designed electronic data base registry.
Duration 30 months (01.04.2022 to 30.09.2024).
Late Preterm Infants born at the participating perinatal centers between 01.04.2022 to 30.09.2024 will be clinically assessed during after birth, included in the Electronic Data Registry and submitted to their corresponding Primary Care Center with a special code.

Objective 4. Late preterm infants will be followed by Pediatricians, Nurses and Midwives of the corresponding Primary Care Attention Center. Electronic Data Registry will be completed at the successive evaluations.
Duration 01.04.2022 to 30.09.2024.
1) The PI will review, update, and analyze the conjoint data of the Electronic Data Registry with the Statistician

(30.6.2023-30.9.2023).
2) The PI will establish the early predictive variables (EPV) targeting altered neurodevelopmental, cognitive and sensorial outcome (01.10.2024-30.10.2024)

Objective 5. To report in scientific meetings and published in peer-reviewed international journals (31.10.2024-31.12.2024 and henceforth)

Objective 6. To write and/or modify Consensus Guidelines for the Follow Up of Late Preterm Infants that will be approved by the Spanish Neonatal Society (SENeo); Spanish Pediatric Primary Care Association (SEPAP), Spanish Pediatric Association (AEP); Spanish Society of Neonatal Nursing (SEEN).

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

In Workpackage 1, the tasks that will be undertaken will allow to implement a clinical guideline for the early detection of predictive factors of neurodevelopmental impairment in infants born preterm between 34+0 and 36+6 weeks' gestation. These tasks will be achieved,
1. Providing primary health professionals with technical knowledge, skills and research tools to early assess patients at risk of neurodevelopmental, cognitive and sensorial impairment (month 3)-
2. Data registry to store all the clinical and analytical data related to the patients' evolving during the first 24 months after birth. (month 3)
3. Follow Up Program strategy for Late Preterm Infants (>34 to 36+6 weeks of gestation) for early detect neurodevelopmental and sensorial deficits. (month 18)
4. Establishing a coordinated Late Preterm Working Group of health professionals including Primary Care Pediatrician, Pediatric Nurses, Neonatologist, Obstetrician, Midwife, and specialists, and early intervention professionals that will decide the commencement of the required therapies for the child on the appropriate timing to improve his/her outcome (moth 18).
5. Publication reporting multivariable analyses of neurodevelopmental milestones, sleeping and eating habits and anthropometry looking for early predictive biomarkers of neurodevelopmental outcome at school age (month 30)
6. Developing a Consensus Guideline for the Integrated Follow Up of Late Preterm Infants to be applied in Primary Care Centers by Pediatricians and Pediatric Nurses- (month 36)

MILESTONES´OBJECTIVE

Brief description and date of delivery Max. 2,250 characters

1. To establish a Follow Up Flow Diagram to identify, recruit, follow and minimize losses of Late Preterm Infants born at the referral centers participating in this program by 31.01.2022
2. To provide Online Follow Up Course and Training Program for health care personnel of Primary Care Centers. This online course is a training initiative of the SENeo in Neurodevelopment. It integrates professionals trained and specialized in assorted areas for the multidisciplinary assessment of the child. The program provides specific knowledge and tools for the assessment of the preterm child and for the early identification of warning signs. 1.01.2022-30.03.2022
3. To design an Electronic Data Register Program to retrieve and analyze data from all recruited patients. 1.01.2022-28.02.2022.
4. Evaluation of the degree of fulfillment of the Program- month 6
5. To perform a statistical analysis of neurodevelopmental milestones, sleeping and eating habits and anthropometry looking for early predictive biomarkers of neurodevelopmental outcome at school age. 1.10.2024 – 31.10.2024
6. Data analysis: The third year of the project will be mainly dedicated to completing follow-up and data analysis. Conventional statistics will be combined with advanced methods and machine learning, supported by data scientists to identify complex relationships (month 30)
7. To write a consensus guideline for the Follow Up of Late Preterm infants that include early predictive biomarkers applicable in the Primary Health Care Centers and sent to the Spanish Neonatal Society, Spanish Pediatric Association and Spanish Neonatal Nursing Society for approval- (month 36)

RICORS Code	RICORS Leader:

DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTVIE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	7	Start Date/Start Event	01/01/2022	End Date/End Event	31/12/2024
Description	NEURODEVELOPMENTAL IMPAIRMENT AND ASSOCIATED RISK FACTORS: PRE-,NEONATAL AND POSTNATAL MEDICAL AND FAMILY CARE INTEVENTIONS TO IMPROVE OUTCOMES.				
Participant Research Groups (Code)	RG3 (RD21/0012/0014), RG5 (RD21/0012/0003), RG4 (RD21/0012/0009), RG6 (RD21/0012/0017), RG2 (RD21/0012/0015), RG14 (RD21/0012/ 0016), RG1 (RD21/0012/ 0001), RG10 (RD21/0012/0006), RG15 (RD21/0012/ 0018), RG20 (RD21/0012/0026)				

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

GENERAL OBJETIVES
Identification of patients at risk to prevent or minimize neurodevelopmental disorders by implementing multidisciplinary measures in a hospital and primary care continuity program.
SPECIFICS OBJETIVES AND TASKES
1. Identification of risk factors associated with neurodevelopmental disorders

2. Program of care continuity from admission and after discharge to guarantee comprehensive multidisciplinary care with the participation of Primary Care, of all neonates at risk of adverse neurodevelopment

3. Implementation of a Family Integrate Care Program (FICare) in Spanish Neonatal Intensive Care Units (NICU)

WORK DESCRIPTION

RELATED TO OBJETIVES 1

This objective will include the following tasks
1. Study of cerebral hemodynamic imaging, macro- microcirculation and oxygen delivery (Cerebral Monitoring Techniques for the prevention of brain injury of prematurity).
2. Design of a predictive model of risk of neonatal brain or intestinal injury based on artificial intelligence using multimodal monitoring of the brain-heart-intestine axis as a strategic ally in the prevention of long-term morbidity in high-risk newborn.
3. To improve the predictive value of neuroimaging (US and MRI) and EEG as validated biomarkers of brain damage that identify patients at high risk of developing neurodevelopmental disorders and help identify the needs for out-of-hospital follow-up.

RELATED TO OBJETIVES 2

This objective will include the following tasks
This Objective will be developed with the very close participation of Primary Care researchers.
1. To design and Develop a systematic / structured evaluation program for the follow-up of the newborn at high risk of neurodevelopmental disorders
2. Prepare guidelines for a Monitoring and Neurodevelopment Committee that will serve as a basis for coordinating care with Primary Care, Early Care and psychopedagogues
3. Develop an design an early intervention program in the motor, neurocognitive and visual area
4. To design and develop a nutrition optimization program
5. To designn and developa monitoring program for neonates who have suffered nosocomial bacterial and viral infections
6. To design and develop of the e-health technological innovation program
7. To design and develop of a multidisciplinary calendar for follow-up and hospital and primary care evaluations of newborns with operated congenital heart disease
8. To design and develop of a multidisciplinary hospital follow-up calendar and primary care for newborns with operated congenital heart disease
9. To design and develop of a calendar for multidisciplinary hospital follow-up and primary care of newborns with

bronchopulmonary dysplasia
10. To design and develop a multidisciplinary hospital follow-up calendar and primary care of newborns with congenital diaphragmatic hernia
11. To design and develop a multidisciplinary calendar of multidisciplinary hospital follow-up and Primary care of the premature newborn less than 28 weeks of gestational age
12. To design and develop a calendar of multidisciplinary hospital follow-up and Primary Care of the newborn of the premature newborn between 28 and 32 weeks of gestational age
13. To design and develop a multidisciplinary hospital follow-up calendar and Primary Care of the newborn with hypoxic-ischemic encephalopathy

RELATED TO OBJETIVES 3

This objective will include the following tasks:
1.To co-design (involving families, clinical staff, primary care pediatricians , economists, psychologists, sociologists and relevant stakeholders) a rigorous, but flexible unified protocol, that can be tailored for the scaling up and adapting FICare to new cultural and socioeconomic contexts. Will be included and two implementation levels (RISEinFAMILY basic and advanced) will be defined.
2. To assess the impact of RISEinFAMILY on high-risk neonates' health during NICU admission and after discharge (feeding patterns, maturation skills, short-term main neonatal diagnoses and longterm neurodevelopment and infant's general health) and to provide evidence of the benefits of the FICare model on the infants.
3. To assess the impact of RISEinFAMILY on families and healthcare professionals from a psychological, social and cultural (including equality & gender issues) perspective through mixed methods research.
4. To undertake a value of implementation analysis of FICare model in the global setting, evaluating not only those benefits related to babies' health, but also the associated cost, parents satisfaction and healthcare professionals' burnout levels.

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

1. Report through a publication and a guide if the procedure used is a reliable model capable of predicting early the presence of compromised blood flow to the organs (brain and intestine), which would allow modulating some modifiable risk factors for structural injury of tissues, and evaluate the injury and its multidisciplinary follow-up in hospital and in Primary Care after discharge (month 30)
2. Report of the keys to obtain a better predictive value of neuroimaging (US, MRI) and EEG as validate biomarkers of brain damage that identify patients at high risk of developing neurodevelopmental disorders and identify appropriate follow-up after discharge (month 12)
3. Clinical guide / publication for the adequate management of newborns in the NICU with cardiovascular instability. (Month 24)
4. Report of action for multidisciplinary prevention, early detection and follow-up with special attention to the involvement of Primary Care (Month 30)
5. Clinical guidelines for a multidisciplinary hospital follow-up calendar and Primary Care of the newborn with risk of neurodevelopment impairment (Month 20)
6. The dissemination strategy planned will be designed and tailored during the project to embrace the project results for the scientific community, health and education systems' stakeholders and policy-makers and, particularly, to the target group formed by families of potential high-risk neonates. (month 30-33)
7. To develop FICare online platform and training materials, which will be translated into the required languages and cultural context, and to deliver training to both healthcare professionals and famílies (Month 24)

MILESTONES´OBJECTIVE

Brief description and date of delivery Max. 2,250 characters

1. Publication and a guide if the procedure used is a reliable model capable of predicting early the presence of compromised blood flow to the organs (brain and intestine), and evaluation of the injury and its multidisciplinary follow-up in hospital and in Primary Care after discharge (Inter analysis and month 30)
2. Evaluation of the keys to obtain a better predictive value of neuroimaging (US, MRI) and EEG as validate biomarkers of brain damage (Inter analysis and month 12)
3. Evaluation of the Clinical guide / publication for the adequate management of newborns in the NICU with cardiovascular instability. (Interm analysis and Month 24)
4. Evaluation of the action for multidisciplinary prevention, early detection and follow-up with special attention to the involvement of Primary Care (Inter analysis and Month 30)
5. Evaluation of the Clinical guidelines for a multidisciplinary hospital follow-up calendar and Primary Care of the newborn with risk of neurodevelopment impairment (Interm analysis and Month 20)
6.To carry out a baseline analysis of current procedures for neonatal care in the participant NICUs in order to identify the

needs, wishes and requirements of all stakeholders involved in neonatal care (Month 6 and 12).
7. Evaluation of the FiCare implementation according to the specificities of each context: commitment levels (basic / advanced), procedures, training methodology and materials, evaluation framework for the overall project's approach, so all data will be comparable between sites (Inter analysis and Month 30)
8. Verification of the necessary arrangements to achieve the approval from the corresponding research ethics committees in each site will be made (Month 6)
9. To assess the overall impact of FIcare model -from the clinical, social, economic, psychological and cultural point of view- on infants' health, parents and healthcare professionals to extract conclusions of the benefits of implementing FICare program independent of the context or level of NICU care and points for improvement (gender and equality issues will be specifically addressed). A value of implementation analysis of the model will be performed, which will be decisive to inform decision makers (Inter analysis and month 30)

RICORS Code	RICORS Leader:

DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTVIE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	8	Start Date/Start Event	01/01/2022	End Date/End Event	31/12/2024
Description	BREASTFEEDING AS PROMOTIONAL HEALTH ACTIVITY				
Participant Research Groups (Code)	RG4 (RD21/0012/0009), RG2 (RD21/0012/00015), RG3 (RD21/0012/0014), RG14 (RD21/0012/0016), RG11 (RD21/0012/0008), RG5 (RD21/0012/0003), RG6 (RD21/0012/0017), RG10 (RD21/0012/0006) and RG16 (RD21/0012/0021)				

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

General Objective

Improve the health of mother and child promoting breastfeeding and the use of human milk from birth up to the age of two.

Specific Objectives

1. To increase exclusive breastfeeding rates for the first six months of live.
2. To increase breastfeeding rates up to the age of two.
3. To increase the use of mother’s own milk and donor milk in sick newborns.
4. To include Primary Care in Human Milk Bank’s networks to improve the recruitment process of human milk donors.
5. To improve the selection and processing of mother’s own milk and donor milk for sick infants.
6. To improve transport and storage conditions of mother’s own milk for working mothers that want to maintain breastfeeding.

Work description

To achieve the related aims of this WP, the network under the PIs supervision will develop the following tasks:

Related to objectives 1 and 2.
• To promote the Baby-friendly Hospital Initiative (BFHI)-UNICEF accreditation for both Healthcare Centers and Hospitals. The aforementioned accreditation has proven consistently that it increases and prolongs exclusive and mixed breastfeeding rates. The BFHI-Unicef accreditation involves the implementation of a series of measures based on evidence with proven efficacy. This accreditation is defined as a project to improve quality. We have experience in the accreditation and reaccreditation of BFHI-UNICEF centers. We have the support of IHAN-UNICEF to carry out this project both from an operational and research point of view (supporting document is attached). In IHAN-UNICEF, civil society, through breastfeeding support groups, and professional scientific associations of nurses, midwives and doctors are represented.

• To establish the correlation between the accreditation phase and the improvement in breastfeeding rates.
• Development or application of indicators to measure the evolution of breastfeeding rates in the collaborating centers. For example OMS and IHAN breastfeeding survey.

Related to objective 3.
• To improve the skills of the staff to support human milk expression for mothers with admitted children that cannot breastfeed directly.
• Specific workshops will be developed for mothers to improve their ability to express milk
• To facilitate the access to donor milk for all neonatal intensive care units strengthening the Human Milk Bank's Network. There are still units that do not have donated milk, therefore the network of human milk banks must be strengthened and expanded. We have the support of the Spanish Association of Human Milk Banks (supporting document is attached).
• Since effective milk extraction is directly related to the duration of breastfeeding, the same indicators mentioned in objectives 1 and 2 will be used, but applied specifically to the population of mothers whose children are admitted to neonatal units. In addition, the frequency of children who receive only breast milk during their admission (either donated or from their own mother) will be measured.

Related to objective 4.
• To expand Human Milk Bank's network including Primary Care centers and Satellite Centers of Human Milk for donors recruitment and milk collection. Until now, only Hospitals are part of Human Milk Bank's network.
• To perform staff training and Primary Care centers accreditation.
• As an indicator, the measurement of the volume of milk collected in the milk banks will be used before and after the inclusion of the primary care centers.

Related to objective 5.

• Development of procedures to produce special preparations with human milk to treat certain sick newborn pathologies. Both expressed mother's own milk and donor milk for sick infants require different procedures that have an impact on its quality, especially regarding immunomodulatory and infection protective properties. The current line of work will contribute in improving human milk processing so that the most vulnerable infants can receive human milk with all its properties preserved.
• Development of new technologies to adapt human milk to the specific needs of infants with different pathologies.
• As an indicator, the quality of donated milk will be used before and after the introduction of new guidelines or new technologies.

Related to objective 6.

• To identify the best actions to maintain the milk in optimal conditions (like in objective 5) to minimize the impact in breastfeeding caused by the return to work. After maternity leave when nursing women return to work, milk expression to maintain breastfeeding should be done during working hours. This milk must be stored in the workplace, then transported and then stored once again at home. Those steps affect the quality and safety of the milk.
• Support the implementation of breastfeeding workshops accessible to all mothers.
• Since effective milk extraction is directly related to the duration of breastfeeding, the same indicators mentioned in objectives 1 and 2 will be used, but applied specifically to the population of mothers women returning to work.

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

Related to objective 1.
Exclusive breastfeeding rate at six months will have increased by at least five points.(24month)
Publication a collaborative paper with IHAN-Unicef (24month)
Related to objective 2.
After the start of the Project, in the participating centers the breastfeeding rate will have increased by at least five points.(24 month)
Publication a collaborative paper with IHAN-Unicef (24month)
Related to objective 3.
After the start of the project, the increase in the frequency of breastfeeding at discharge in admitted newborns will be at least five points. (24 month)
Related to objective 4.
At least 10 health centers will have been included in the milk bank network.(12 month)
The milk banks that have Primary Care centers included in their network will have increased the volume of milk collected by

10%. (24 month)
Publication a collaborative paper with with Spanish Association of Human Milk Banks (24month)

Related to objective 5.
Publication of the new guidelines. (24 month)
Publication about new procedures and technology. (24 month)
Related to objective 6.
Development of digital APP for mothers and specific material for workshops.(12 month)

MILESTONES´OBJECTIVE

Brief description and date of delivery — Max. 2,250 characters

Related to objectives 1 and 2.
• At least 2D or 3D BFHI-UNICEF Phase accreditation for Primary Care centers (third year).
• Related to accreditation phase, results of the validated annual surveys about breastfeeding rates from both Hospitals and Primary Care centers (from first year)-
• Development of digital APP to enhance survey's distribution (second year)
• Collaborative papers with IHAN UNicef about the accreditation experience of the Primary Care centers (third year)

Related to objective 3.
• Development of digital APP for professionals and mothers that includes support content about human milk expression and storage in NICUs (second year)-
• Accreditation by Regional Human Milk Banks of new NICUs to collect donor milk for admitted newborn infants (second year)
• Specific material will be developed for workshops for mothers and professionals (first year)

Related to objective 4.
• Protocols for selecting and recruiting donors and human milk collection in Primary Care centers (first year)
• Certification by Regional Human Milk Banks of Primary Care centers to recruit and select donors and to collect and store human milk (second year)
• Publication collaborative scientific papers with Spanish Association of Human Milk Banks about the experience of including Primary Care centers in the human milk bank network (third year)

Related to objective 5.
• Guidelines of standard procedures to process donor milk and elaborate special preparations with human milk for sick infants (defatted milk, high protein milk, etc.) (third year)
• Utility model or patent for developed technologies (third year)
• Publication of scientific papers about the guidelines and the new procedures and technologies developed (third year)

Related to objective 6.
• Development of digital APP for mothers that includes support content to facilitate human milk expression and storage after returning to work and information to improve the safety of the process (first year)
• Specific material will be developed for workshops for mothers (first year).

RICORS Code	RICORS Leader:

DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTVIE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	9	Start Date/Start Event	01/01/2022	End Date/End Event	31/12/2024
Description	FOETAL-INFANT PROGRAMMING OF OBESITY AND RISK OF ADULT CARDIOVASCULAR MULTIMORBIDITY				

Participant Research Groups (Code)	RG8 (RD21/0012/0012), RG9 (RD21/0012/0002), RG5 (RD21/0012/0003), RG11 (RD21/0012/0008) and RG14 (RD21/0012/0016)

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

Main Objective
To improve health in the community through preventive strategies focus on those factors that influence programming towards obesity and cardiovascular risk in children and adults from the beginning of life.

Specific Objectives
1. To monitor growth and body composition parameters in the community in relation to foetal and postnatal programming factors and their dietary and physical activity habits from primary care.
2. To study the cardiovascular risk of different vulnerable populations according to maternal, child and socioeconomic factors.
3. To purpose preventive well-designed strategies to tackle the development of obesity and later cardiovascular diseases at community level from the beginning of life.
4. To promote healthy habits trying to establish maternal and child health in different groups at metabolic risk and with social vulnerability.
5. To draw up guidelines and orientations for the promotion of cardiovascular health in children and adults from primary care.
6. Contribute to the implementation of personalised medicine in primary care systems.
7. To develop digital tools to improve nutritional monitoring in primary care
8. To evaluate the effect of specific dietary changes that may benefit cardiometabolic heath.
9. To evaluate the effect of physical activity on cardiometabolic heath.

Work description
To achieve the related aims of this WP, the network under the PIs supervision will develop the following tasks:
Related to objective 1, 6 and 7. Registration and monitoring anthropometric and body composition variables from primary care in different prospective and retrospective cohorts during childhood and adolescence; as well as obstetric, perinatal, sociodemographic and economic factors and lifestyle behaviours such as eating habits, smoking, sedentary time and physical activity at different stages of life that may program the progression towards excess of body weight and adiposity and their comorbidities, from the beginning of life to adulthood. Complex analyses of all variables will then be carried out to identify and prioritise those that add the greatest risk to adult health using machine learning and artificial intelligence tools.

Related to objective 2, 6 and 7. To assess cardiovascular risk in children and adolescents through screening programmes in primary care, detecting vulnerable populations with multiple risk factors as a grouping or 'cluster of factors' among those identified from objective 1. In individuals classified as being at risk, a cardiovascular study will be carried out to check the concordance between the screening and the objective findings, identifying those who require follow-up and treatment.
Related to objective 3, 4 and 6. Implementation of community intervention programmes for the prevention from primary care of cardiometabolic risk and obesity from the beginning of life, as well as their risk factors and comorbidities. To this end, a specific training and accreditation programme will be carried out for primary care health professionals (doctors and nurses) focused on health promotion through the monitoring of the variables contemplated in the previous objectives, advice on protective or risk factors, and detection and treatment of subjects identified as susceptible before multimorbidity progresses.

Related to objective 5. With the results obtained from the previous objectives, and as support for the intervention programmes, guidelines and orientations will be developed for the promotion from primary care of cardiovascular health in children and adults, as well as the prevention and treatment of obesity and its comorbidities. These guidelines and orientations will remain as integrated structural material for healthcare activity in primary care.

Related to objective 8. To carry out nutritional clinical trials in subjects with identified a number of cardiometabolic risk factors with different dietary components that may be useful for their health improvement.
Related to objective 9. Similarly to those related to objective 8, to carry out physical activity interventions to evaluate changes on cardiometabolic health the quality of life.

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

Deliverable 1: Related to objectives 1 and 7.
- Creation of a data-base: Registration in nationally representative cohorts of the prevalence of overweight, obesity, energy-balance related behaviours (EBRB) such as sedentary lifestyles, physical activity, dietary and sleep patterns together with social demographics (vulnerability) and different obstetric and perinatal factors that may predict the onset of excess weight and cardiometabolic disease throughout life. These data may be used in a recent future for bigger data analyses (BIG-DATA)

January 2022-December 2023
Deliverable 2: Related to objective 2, 6 and 7.
- Validated algorithm screening for the identification of individuals at cardiovascular risk from early stages of life in primary care.
September 2022-June 2023

Deliverable 3: Related to objective 3, 4, 6 and 7.
- Recommendations and guidelines for the implementation of community intervention programmes* for the prevention and treatment of cardiometabolic risk and obesity early in life from primary care.
September 2022- June 2023
- Specific training and accreditation programme for primary care health professionals (doctors and nurses) on the identification of risk factors and prevention of obesity and its comorbidities.
January 2022-June 2022

Deliverable 4: Related to objective 5, 6, 8 and 9.
- Guidelines and recommendations for public health practicioners for the promotion from primary care of cardiovascular health in children and adults, as well as the prevention and treatment of obesity and its comorbidities. *
January 2024-December 2024
Related to objective 8 and 9.
- e-Health Assessment tool for the identification of nutritional and physical activity that may help to better understand what is the real situation and motivation of children early ages and how can be objectively monitoring them*.
September 2022-June 2023
- e-Health Assessment tool for the surveillance of dietary and physical interventions for prevention of cardiovascular diseases in children*.
January 2024-June 2024
*The deliverables marked with an asterisk, will entail the publication of a scientific article, in addition to a clinical guide that will serve from primary care for obstetric-pediatric monitoring.

MILESTONES´OBJECTIVE

Brief description and date of delivery — Max. 2,250 characters

1. Data management: kick-off and follow-up meetings will take place monthly
2. To set the protocols and SOP for all the procedures and determinations (month 3)
3. Registry of the whole perinatal period health for the mother-child binomial to be used both in recent and later analyses or studies (it´s a continuous task)
4. Summary of data on the best tools to be used for screening and for interventions on EBRBs (month 24)
5. Development of CV risk and surveillance app for children at risk (month 24)
6. Validation of app (month 30)
7. Data analysis: The third year of the project will be mainly dedicated to completing follow-up and data analysis. Conventional statistics will be combined with advanced methods and machine learning, supported by data scientists to identify complex relationships (month 30)
8. Dissemination: the last 3 months will be committed to scientific reports, publications and dissemination of results to the scientific community and society (month 36)

RICORS Code	RICORS Leader:

DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTVIE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	10	Start Date/Start Event	01/01/2022	End Date/End Event	31/12/2024
Description	PREVENTION, CARE AND FOLLOW-UP WITH CONTINUITY OF CARE OF PEDIATRIC PATIENTS WITH SERIOUS PATHOLOGY: COORDINATION AND INTEGRATION OF PRIMARY AND HOSPITAL CARE.				

Participant Research Groups (Code)	RG7 (RD21/0012/0011), RG12 (RD21/0012/0025), RG13 (RD21/0012/0020), RG11 (RD21/0012/0008), RG3 (RD21/0012/0023), RG14 (RD21/0012/0016) and CA9

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

GENERAL OBJECTIVE
To study the effect of a coordinated hospital and primary care program on the prevention, early detection and monitoring of evolution and sequelae of childhood chronic serious diseases

ACHIEVABLE RESULTS
1. To determine the prevalence of chronic serious diseases in children in Spain creating national registries.
2. To determine the prevalence, characteristics and medical and social needs of technology dependent children in Spain creating a national registry.
3. To evaluate the effect of preventive measures to reduce the incidence of accidents and cardiac arrest in high-risk children.
4. To evaluate the efficacy of nutritional and lifestyle treatments on neurological health and complications after severe diseases, and to develop new primary care nutritional and healthy strategies that may collaborate for the monitoring and treatment.
5. To evaluate the effect of a Primary and Hospital Coordinated Care Program in technology dependent children.
6. To evaluate the effect of telemonitoring and medical teleconsultation in the follow up of children with chronic serious illnesses.
7. To determine the need of palliative care and ethical issues in chronic serious diseases in children in a home care program.
8. To evaluate the impact of early diagnosis and follow-up of rare genetic and metabolic disease in children

SPECIFIC OBJETIVES AND TASKS
SO1: To identify and follow populations with risk factors for major neurodevelopmental impairment and psychological, visual, auditory disabilities in childhood (cardiac arrest, treatment with ECMO, pediatric stroke, brain trauma, postcardiac surgery, brain infections, long-term hospital stay, rare genetic and metabolic disease, esophageal and diaphragmatic surgical malformations).To study the usefulness of methods for early detection of risk factors and neurological disorders: neuroimaging methods (ultrasound, CT, MRI, PET) cerebral blood flow, NIRS, EEG, biochemical biomarkers, maturation of circadian rhythms. To develop nutritional and home health monitoring and treatment of patients with severe neurological diseases (PCI, severe encephalopathies and epilepsy).
Tasks
In order to achieve the related aims of this WP, the network will develop the
following tasks:
• To long-term follow up patients included in the multicenter prospective observational study of cardiac arrest in children (PACHIN) PI18-001632 of ISCIII program. To follow up children treated with hypothermia as prevention of acute neurological and long term after cardiac arrest in children.
• To design and development of a multicenter prospective observational registry with long-term follow up of risk factors for neurologic disability after stroke in children.
• To design and development of a multicenter prospective observational registry of risk factors for neurologic impairment secondary to high-risk congenital heart disease, cardiac surgery and children treated with extracorporeal membrane oxygenation (ECMO) therapy with long-term follow up.
• To design and development of a multicenter prospective observational registry of children with long-term hospital stay for major neurodevelopmental impairment and psychological, visual and auditory disabilities.
• To evaluate and implement nutritional and lifestyle tools and ketogenic diets as domiciliary treatment for patients with severe neurological diseases.
• To evaluate neurological long-term sequelae in children with esophageal atresia or congenital diaphragmatic hernia, especially in those requiring advanced respiratory support during newborn period.
• To evaluate the results of participation of primary care health worker in the early diagnosis and follow-up of rare genetic and metabolic diseases in children

Lead partners
This objective will be led by Gregorio Marañón Group. Investigation groups of Asturias, Galicia, Granada, Cantabria,Hospital La Paz and Gregorio Marañón will participate in the coordination of the registries and follow-up of the patients.

SO2. To determine the prevalence, characteristics and medical and social needs of technology dependent children in Spain creating a national registry.
Tasks
In order to achieve the related aims of this WP, the network will develop the

following tasks:
• To design and development of a multicenter prospective observational registry of home care high technology dependent children in Spain
• To evaluate the medical and social needs and the quality of life of children and families in home care high technology dependent children and to compare with previous Spanish study (SEPAR 024/2009) and international registries.
Lead partners
This objective will be led by Gregorio Marañón Group. Investigation groups of Asturias, Galicia, Hospital La Paz and Gregorio Marañón will participate in the coordination of the registries and follow-up of the patients.

SO3. To evaluate the effect of prevention and treatment methods to reduce the incidence of accidents, cardiac arrest in children and neurological disorders and sequelae in pediatric risk population.
Tasks
In order to achieve the related aims of this WP, the network will develop the following tasks:
• To design and evaluate specific courses and workshops using medical simulation to perform the health education of children, parents and relatives of high-risk children and general population on prevention and first aid in accidents, cardiac in Primary Care and Hospital settings
• To perform recommendations of prevention and first aids in accidents and complications of serious diseases in children.
Lead partners
This objective will be led by Galicia Group. Investigation groups of Asturias, Galicia and Gregorio Marañón will participate in the design, development and evaluation of the education activities.

SO4. To evaluate the effect of a Primary Care and Hospital Care Coordinated Program in technology dependent children with the participation of families and patient associations.
Tasks
In order to achieve the related aims of this WP, the network will develop the following tasks.
• To design and develop an integrated and coordinated follow-up program including Hospital and Primary Care services to technology dependent children (respiratory assistance, artificial nutrition, high risk children of cardiac arrest)
• To integrate families and patient associations in de design, development and control of the program
• To design and evaluate a home care hospitalization program in technology dependent children.
Lead partners
This objective will be led by Gregorio Marañón Group. Investigation groups of Asturias, Galicia, Cantabria and Gregorio Marañón will participate in the coordination and evaluation of the program.

SO5. To evaluate the effect of telemonitoring and medical teleconsultation in the follow up of children with chronic serious illnesses.
Tasks
In order to achieve the related aims of this WP, the network will develop the following tasks.
• To design and evaluate a program telemonitoring and medical teleconsultation in technology dependent children and high-risk children (complications, reduction in hospitalizations, children and parent satisfaction).
• To evaluate the different methods of telemonitoring and teleconsulting to perform recommendations for high-risk children.
Lead partners
This objective will be led by Asturias Group. Investigation groups of Asturias, Galicia, Cantabria, Hospital La Paz and Gregorio Marañón will participate in the patient follow-up and evaluation of the program.

SO6. To determine the need of palliative care and ethical issues in chronic serious diseases in children in a home care program with continuity of care with Primary Care
Tasks
In order to achieve the related aims of this WP, the network will develop the following tasks.
• To perform an evaluation of palliative care in chronic serious diseases in children.
• To perform specific recommendations of ethical issues in chronic serious diseases in children on a home care program.
Lead partners
This objective will be led by Galicia Group. Investigation groups of Asturias, Galicia, Cantabria, Niño Jesús and Gregorio Marañón will participate in the patient follow-up and evaluation of results.

SO7. To determine the prevalence, characteristics and medical and social needs of children with diabetes in Spain creating a national registry.
Tasks
In order to achieve the related aims of this WP, the network will develop the
following tasks:
• To design and development of a multicenter prospective observational registry of children with diabetes in Spain
• To evaluate the medical and social needs and the quality of life of children with diabetes and their families and to compare with previous Spanish and international registries.
Lead partners
This objective will be led by Asturias Group. Investigation groups of Asturias, Galicia and Gregorio Marañón will participate in

the coordination of the registries and follow-up of the patients.

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

At the end of the program the following deliverables will be published
1. Report of the long-term follow up of multicenter study of cardiac arrest in children (PACHIN). (36 months)
2. Report of national registry of pediatric stroke in children (18 and 36 months)
3. Report of the multicenter prospective observational registry of high-risk congenital heart disease, cardiac surgery, esophageal or diaphragmatic surgery and children treated with extracorporeal membrane oxygenation (ECMO) therapy (18 and 36 months)
4. Report of the multicenter prospective observational registry of home care high technology dependent in Spain (18 and 36 months)
5. Report of multicenter registry of rare genetic and metabolic disease in children (18 and 36 months)
6. Clinical guidelines for prevention, early detection and follow-up of chronic serious diseases children (diabetes, chronic renal failure, celiac disease, prematurity (20 months)
7. Guidelines for nutritional and health monitoring of children with severe neurological diseases, esophageal atresia and congenital diaphragmatic hernia (20 months)
8. Nutritional protocol for the treatment of children with severe epilepsy (24 month)
9. Report of the results of education activities of health care education (36 month)
10. Recommendations of education activities of health care education in high risk children and families (20 month)
11. Report of the evaluation of the Primary Care and Hospital Care Coordinated Program in technology dependent children (18 and 36 month)
12. Report of the evaluation of technologies of telemonitoring and teleconsulting in technology dependent children with chronic serious disease children (18 and 36 month)
13. Report of the evaluation of the program telemonitoring and medical teleconsultation in technology dependent children (18 and 36 month)
14. Report of recommendations of ethical issues in chronic serious diseases in children on a home care program (24 month)

MILESTONES´OBJECTIVE

Brief description and date of delivery Max. 2,250 characters

1. First evaluation of data collection about the registries of: 1) pediatric stroke in children, 2) high-risk congenital heart disease, cardiac surgery, esophageal or diaphragmatic surgery and children treated with extracorporeal membrane oxygenation (ECMO) therapy, 3) home care high technology dependent Children 4) rare genetic and metabolic disease children and 5) program telemonitoring and medical teleconsultation in technology dependent children will be performed at 18 month

2. The clinical guidelines for prevention, early detection and follow-up of chronic serious diseases children (diabetes, chronic renal failure, celiac disease, prematurity will be finished by the 18 month.

3. The clinical guidelines for nutritional and health monitoring of children with severe neurological diseases, esophageal atresia and congenital diaphragmatic hernia will be finished by the 18 month.-

4. The recommendations of ethical issues in chronic serious diseases will be finished at 22 month-

5. Final evaluation of data collection about the registries of) pediatric stroke in children, 2) high-risk congenital heart disease, cardiac surgery, esophageal or diaphragmatic surgery and children treated with extracorporeal membrane oxygenation (ECMO) therapy, 3) home care high technology dependent Children 4) rare genetic and metabolic disease children and 5) program telemonitoring and medical teleconsultation in technology dependent children will be performed at will be finished at 30 month-

6. Educational material (videos, books, etc..) will be finished by 30 month

7. Workshops for healthcare workers to transfers research results and present best practice guidelines will be completed by month 32

RICORS Code	RICORS Leader:

DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTVIE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	11	Start Date/Start Event	01/01/2022	End Date/End Event	31/12/2024
Description	PRIMARY CARE IDENTIFICATION OF CHILDREN AT RISK OF CHRONIC DIGESTIVE AND RENAL PATHOLOGIES AND INTERVENTIONS FOR THE PREVENTION OF DISEASE EVOLUTION.				
Participant Research Groups (Code)	RG11 (RD21/0012/0008), RG8 (RD21/0012/0012), RG9 (RD21/0012/0002), RG7 (RD21/0012/0011), RG16 (RD21/0012/0021) RG12 (RD21/0012/0025) and RG13 (RD21/0012/0020)				

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

GENERAL OBJECTIVE

Identification of mechanisms that improve treatment and follow up of children chronic digestive and renal pathologies and to stablished new protocols for the identification of subjects at risk for the prevention of disease evolution from primary health care units.

ACHIEVABLE RESULTS

2. Evaluation of the influence of nutritional components on celiac patients
3. Development of nutritional strategies for the follow up of celiac patients.
4. To establish primary care protocols for the follow-up and treat paediatric patients suffering food allergies
5. To identify a possible relationship in the development of food allergy between mothers and children.
6. Identification of new biomarkers for the early diagnosis of chronic renal pathology.
7. To stablish a new protocol to implement in paediatric primary care as a tool for the identification of vulnerable subjects at risk of chronic comorbidities of chronic kidney disease.

OBJETIVES AND TASKS

To achieve the related aims of this objecive, the network under the PIs supervision will develop the following tasks:

11.1: Evaluation of the influence of nutritional components on celiac patients, and development of nutritional strategies for the follow up of celiac patients.
Task: We will evaluate the influence of nutritional intervention on the evolution of the disease and its consequences. We will measure nutritional, biochemical and quality of life parameters of celiac patients in order to stablish the state of the pathology. These data will be publishing in international journals. We will improve questionnaires to evaluate adherence to nutritional recommendations for celiac disease in school canteens. We will prepare guidelines and protocols that will help and improve the following up of celiac patients by primary care professionals and in school canteens.

11.2: To identify a possible relationship in the development of food allergy between mothers and children.
Task: We will follow up of children of mothers with food allergy in children up to 2 years from the NELA cohort. With these data we will be able to stablish new tools and guidelines for the identification of vulnerable children at risk of food allergy to be implemented in obstetrics and paediatric primary care services. These data will be publishing in international journals.

11.3: To study, follow-up and treat paediatric patients suffering food allergies: establishment of primary care protocols.
Task: We will follow up paediatric patients suffering food allergies, analysing clinical, biochemical and immunological parameters that help the understanding of the pathology.These data will be publishing in international journals. With these

data we will be able to stablish new tools for the treatment of children at risk of food allergy by paediatric primary care professional. In addition, we are carrying out pilot desensitization of paediatric patients suffering food allergies. We will improve protocols for these processes in the hospital in collaboration with primary care professionals, who are the ones who carry out the follow-up of these patients. Thus, it is necessary to design protocols for follow-up and action of desensitized children.

11.4 Identification of new biomarkers for the early diagnosis of chronic renal pathology.
Task: We propose a prospective study in a pediatric population with chronic kidney disease. Anthropometric, clinical and biochemical parameters will be evaluated to determine the presence of chronic kidney disease and to allow its classification according to degrees of severity, taking into account the glomerular filtration rate and the presence of albuminuria in urine according to the KDIGO 2012 criteria. In addition, inflammatory, metagenomic and metabolomic biomarkers will be determined, and statistically correlated with classical biomarkers, in order to understand the pathophysiology of the disease, and to find out new early prognosis biomarkers that allow the identification of vulnerable subjects at risk of severe evolution of chronic kidney disease and its comorbidities.We will prepare a follow-up clinical protocol for implementation in primary care paediatricians services. These data will be publishing in international journals (24 months).

11.5 To stablish a new protocol to implement in paediatric primary care as a tool for the identification of vulnerable subjects at risk of chronic comorbidities of chronic kidney disease.
Task: Due to the seriousness of the cardiovascular and neurological comorbidities that CKD can entail, it is necessary to identify early biomarkers that allow the identification of the first stages of these complications in order to prevent and treat them before they evolve unfavourably. For this purpose, integration of classical clinical and biochemical data with new techniques information, using artificial intelligence techniques, will allow us to provide a holistic view of the problem that may allow the identification of vulnerable children at risk of severe neurological and cardiovascular comorbidities for their early prevention. We will stablish new guidelines for the identification and personalized treatment of these subjects, easily implemented in primary care services.

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

Related to objective 11.1.
• Report through a publication environmental factor influencing the evolution of celiac pathology (month 24)
• Improvement of questionnaires for the evaluation of the adherence to celiac disease nutritional recommendations in school canteens (24 months).
• Nutritional protocols for the treatment of celiac patients in primary care officesand in school canteens(month 30)
Related to objective 11.2.
• Report through a publication the influence of pregnancy factors on food allergy development (month 36)
Related to objective 11.3.
• Report through a publication new parameters involved in the development and evolution of food allergies (month 24)
• Clinical guide / publication for the improvement of food allergy management (month 30)
• Clinical guide for the adequate management of food allergy desensitization protocols(month 36)
Related to objective 11.4.
• Report through a publication new biochemical parameters useful for the diagnosis and following up of chronic kidney disease (month 24)
Related to objective 11.5.
• Clinical guide / publication describing criteria for early diagnosis of renal chronic patients at risk of neurological comorbidities (Month 36)
• Clinical guide / publication describing criteria for early diagnosis of renal chronic patients at risk of cardiovascular comorbidities (Month 36)

MILESTONES´OBJECTIVE

Brief description and date of delivery Max. 2,250 characters

Related to objective 11.1.
- Data collection about environmental factor influencing the evolution of celiac pathology, will be finished by 24 months
- Data collection about the adherence to celiac disease nutritional recommendations in school canteens, will be finished by 24 months
- Nutritional protocols for celiac patients will be finish by 30 months

Related to objective 11.2.

- Description of the influence of pregnancy factors on food allergy development will be finished by 36 months

Related to objective 11.3.
- Description of parameters involved in the development and evolution of food allergies will be finished by 24 months
- Best-practice guides about the improvement of food allergy management will be finished by 30 months
- Best-practice guides about food allergy desensitization protocols will be finished by 36 months

Related to objective 11.4.
- Description of new biochemical parameters useful for the identification of vulnerable children at risk of severe chronic renal disease, their diagnosis and following up will be finished by 24 months

Related to objective 11.5.
- Description of criteria for early diagnosis of renal chronic patients at risk of neurological and cardiovascular comorbidities will be finished by 36 months

RICORS Code	RICORS Leader:

DESCRIPTION OF THE RESEARCH ACTIVITY PROGRAMME
WORK PACKAGES (WP), DELIVERABLES AND MILESTONES BY OBJECTVIE

Max. 3 pages per objective (14,850 characters)

OBJECTIVE	12	Start Date/Start Event	01/01/2022	End Date/End Event	31/12/2024
Description	PROMOTING A PERSONALISED AND FAMILY-CENTRED MATERNAL AND INFANT PRIMARY HEALTH CARE: IMPROVING SHARED DECISION-MAKING, GENDER-SENSITIVE APPROACHES AND DIGITAL TOOLS.				
Participant Research Groups (Code)	RG15 (RD21/0012/0018), RG3 (RD21/0012/0014), RG12 (RD21/0012/0025), RG6 (D21/0012/0017), RG5 (RD21/0012/0003) and RG1 (RD21/0012/0001)				

DESCRIPTION OF OBJECTIVE´S WORK PACKAGE

Where appropriate broken down into tasks. Indicate Lead partner and role of participants. Max. 11,550 characters

General Objective:

Employ digital tools to foster a personalised and family-centred approach to maternal and infant primary healthcare, including sensitivity to gender, ethnic and other forms of diversity end users (mothers, fathers and children), as well as the promotion of shared decision-making between them and the healthcare professionals who work with them.

Specific Objectives and tasks
SO.1. Understand what end users (families and children) of maternal and infant primary healthcare believe they need to achieve personalised and family-centred health and well-being.
• Figure out how users of maternal and infant primary healthcare perceive health services, with special attention to gender issues and perceptions of shared decision-making through: (1) a survey of end users, (2) focus groups with families, (3) semi-structured interviews with families, (4) participatory activities with children.
• Design infographics to inform maternal and infant primary healthcare providers about families' and children's perceptions of healthcare services.
• Produce a short video to transfer research results to healthcare professionals, end users and the larger community.
• Develop an assessment service through discussion groups with parents and families to disseminate research results and create a reflective space regarding children's healthcare issues and lifestyle behaviours such as eating and drinking habits, sedentary lifestyle, and physical activity.

SO.2. Highlight and promote what healthcare professionals think and if and how they use gender and ethnic approaches with

their patients and shared decision-making with them in their everyday practices.
• Determine what maternal and infant primary healthcare professionals know about, and if and how they use, gender and ethnic approaches and shared decision-making in their everyday practices, via: (1) a survey to health care professionals, (2) participant observation in maternal and infant primary healthcare facilities, (3) semi-structured interviews with both professionals and end users.
• Design and produce two short videos to transfer research results to healthcare professionals, families, and society at large regarding gender-and ethnically sensitive approaches and shared decision-making.
• Improve gender- and ethnically sensitive approaches and shared decision-making between healthcare professionals via: (1) focus groups with families and healthcare professionals together.
• Design and produce two best-practice guides about gender- and ethnic to sensitive approaches and shared decision-making in maternal and infant health in primary care facilities.
• Design and execute two workshops for healthcare professionals to share research results and present the best practices guides.

SO.3. Assist end users of maternal and infant primary healthcare services in better understanding and navigating health systems and interacting with their care providers through digital tools designed to provide a more personalised and family-centred healthcare experience at home, at work, at schools and in the community.
• Evaluate how digital tools are currently being used in maternal and infant healthcare in primary care systems.
• Create an app to foster personalised communication between healthcare professionals and end users, including medical tele-consultation.

DELIVERABLES´ OBJECTIVE

Brief description and date of delivery. Max. 2,250 characters

Deliverable 1 (related to SO.1)
End-users' survey: month 12
1 Focus group with parents: month 18
1 Focus group with children: month 18
1 Focus group with healthcare professionals: month 18
40 Semi-structured interviews with parents: month 18
2 Workshops with children to assess their perceptions and understandings of shared decision-making and ethnically approaches in primary healthcare services (2x10 children): month 20
Report on parents' and children's perceptions of gender, shared decision-making and ethnically approaches in primary healthcare services: month 24
Academic article manuscript: month 32
Deliverable 2 (related to SO.1)
Infographics to inform healthcare professionals about parents and children perceptions: month 24

Deliverable 3 (related to SO.1)
2 Short videos (aprox. 6 min) to disseminate research results to parents and children: month 24
Deliverable 4 (related to SO.2)
Report on maternal and infant healthcare professionals' perceptions of gender, shared decision-making and ethnically approaches in primary healthcare services Healthcare professionals' survey: month 12
Report on participant observation in primary healthcare services: month 18
30 Semi-structured interviews with healthcare professionals: month 18
Academic article manuscript: month 34

Deliverable 5 (related to SO.2)
Short video (6 min. aprox.) to transfer research results to healthcare professionals: month 24
Deliverable 6 (related to SO.2)
Best practice guide about gender and ethnic equality perspectives in healthcare: month 30

Deliverable 7 (related to SO.2)
3 Workshops for healthcare professionals (aprox. 3x15 participants): month 30

Deliverable 8 (related to SO.2)
Best practice guide about shared decision-making perspectives in healthcare: month 30

Deliverable 9 (related to SO.3)
Assessment report of current digital tools: month 24

Deliverable 10 (related to SO.3)

App for monitoring maternal and infant health and wellbeing: month 36

MILESTONES´OBJECTIVE

Brief description and date of delivery Max. 2,250 characters

This objective promotes gender- and ethnically sensitive approaches and shared decision-making perspectives within infant and maternal healthcare systems in the framework of improving users' care and inclusion through participatory processes, including providing strategies and guidelines for interactions between health professionals and users.

Data collection about families and healthcare professionals' perspectives on gender- and ethnically sensitive approaches and shared decision-making, will be finished by 18 months.

The evaluation of current digital methods of communication between healthcare professionals and end users will be finished by month 24.

Infographics and videos for disseminating research results to families, healthcare professionals and communities will be finished by 24 months.

The best-practice guides about how to introduce gender- and ethnically sensitive approaches and shared decision-making, designed in a collaborative process with families, will be finished by month 30.
Workshops for healthcare professionals to transfer research results and present best-practice guides will be completed by month 30.

An app to for a direct communication between healthcare professionals and users will be finished by month 36.

RICORS Code	RICORS Leader:
RD21/0012/0001	Elisa Llurba Olivé

LIST OF DELIVERABLES

DELIV. Nº	DELIVERABLE NAME	OBJECTIVE	DISSEMINANTION LEVEL	DELIVERY DATE
1	Report on the utility of the incorporation of glycated hemoglobin HbA1c and serum glucose at hazard in the first trimester for the diagnosis of GDM in high risk GDM women	1	SCIENTIFIC COMMUNITY	Month 36
2	Educational nutritional program to be used by midwifes to improve nutritional care of pregnant women and high risk of GDM and obese pregnant women	1	SOCIETY	Month 12
3	Report on growth, adiposity and eating behaviour in offspring of GDM	1	SCIENTIFIC COMMUNITY	Month 30
4	Educational nutritional program to improve nutritional care, support breastfeeding and dietary intervention in postpartum GDM women	1	SOCIETY	Month 24
5	Report on neurodevelopment , sleep and eating disorders in offspring	1	SCIENTIFIC COMMUNITY	Month 30
6	Guideline for diagnostic and management of women GDM from first trimester of pregnancy in primary care services	1	POLICY MAKERS	Month 36
7	Guidelines and orientations for the promotion from primary care of health in children from GDMs, as well as the prevention and treatment of obesity and its comorbidities	1	POLICY MAKERS	Month 36
8	Reduction in the incidence of preterm PE by 50%	2	SCIENTIFIC COMMUNITY	Month 30
41	Webinar about consumption of substances of abuse during pregnancy and breastfeeding	5	SCIENTIFIC COMMUNITY	Month 12
42	Guidelines about deleterious effects of environmental contaminants and consumption of substances of abuse during pregnancy	5	POLICY MAKERS	Month 24
43	Inventory about good and best practices to reduce alcohol-related harm among women	5	SCIENTIFIC COMMUNITY	Month 12
44	Recommendations on alcohol exposed pregnancy prevention	5	POLICY MAKERS	Month 24
45	A specific preventive program about prevention of consumption of substances of abuse during pregnancy	5	POLICY MAKERS	Month 36
46	Specific tools about diagnosis and treatment of FASD	5	SCIENTIFIC COMMUNITY	Month 36
47	Algorithm for diagnosis and follow up of children with FASD	5	SCIENTIFIC COMMUNITY	Month 18
48	Specific guidelines for professionals and families about FASD	5	SOCIETY	Month 12
49	Data about the development of program about mental health problems of high complexity	5	SCIENTIFIC COMMUNITY	Month 30

50	A file of a model of maternal and child environmental health program	5	POLICY MAKERS	Month 36
51	A file of a model of intervention unit about maternal and child environmental health	5	POLICY MAKERS	Month 36
52	Providing primary health professionals with technical knowledge, skills and research tools to early assess patients at risk of neurodevelopmental, cognitive and sensorial impairment	5	SCIENTIFIC COMMUNITY	Month 3
53	Data registry to store all the clinical and analytical data related to the patients' evolving during the first 24 months after birth	6	SCIENTIFIC COMMUNITY	Month 3
54	Follow Up Program strategy for Late Preterm Infants (>34 to 36+6 weeks of gestation) for early detect neurodevelopmental and sensorial deficits.	6	SCIENTIFIC COMMUNITY	Month 18
55	Establishing a coordinated Late Preterm Working Group of health professionals including Primary Care Pediatrician, Pediatric Nurses, Neonatologist, Obstetrician, Midwife, and specialists, and early intervention professionals that will decide the commencement of the required therapies for the child on the appropriate timing to improve his/her outcome	6	POLICY MAKERS	Month 18
56	Developing a Consensus Guideline for the Integrated Follow Up of Late Preterm Infants to be applied in Primary Care Centers by Pediatricians and Pediatric Nurses	6	POLICY MAKERS	Month 36
57	Report of the keys to obtain a better predictive value of neuroimaging (US, MRI) and EEG as validate biomarkers of brain damage that identify patients at high risk of developing neurodevelopmental disorders and identify appropriate follow-up after discharge	7	SCIENTIFIC COMMUNITY	Month 12
58	Clinical guide / publication for the adequate management of newborns in the NICU with cardiovascular instability	7	SCIENTIFIC COMMUNITY	Month 24
59	Report of action for multidisciplinary prevention, early detection and follow-up with special attention to the involvement of Primary Care	7	POLICY MAKERS	Month 30
60	Clinical guidelines for a multidisciplinary hospital follow-up calendar and Primary Care of the newborn with risk of neurodevelopment impairment	7	POLICY MAKERS	Month 20
61	The dissemination strategy planned will be designed and tailored during the project to embrace the project results for the scientific community, health and education systems' stakeholders and policy-makers and, particularly, to the target group formed by families of potential high-risk neonates	7	POLICY MAKERS	Month 30-33
62	To develop FICare online platform and training materials, which will be translated into the required languages and cultural context, and to deliver training to both healthcare professionals and families	7	SOCIETY	Month 24
63	Exclusive breastfeeding rate at six months will have increased by at least five points	8	SCIENTIFIC COMMUNITY	Month 24

64	Publication a collaborative paper with IHAN-Unicef	8	SCIENTIFIC COMMUNITY	Month 24
65	After the start of the Project, in the participating centers the breastfeeding rate will have increased by at least five points	8	SCIENTIFIC COMMUNITY	Month 24
66	After the start of the project, the increase in the frequency of breastfeeding at discharge in admitted newborns will be at least five points	8	SCIENTIFIC COMMUNITY	Month 24
67	At least 10 health centers will have been included in the milk bank network	8	SOCIETY	Month 12
68	The milk banks that have Primary Care centers included in their network will have increased the volume of milk collected by 10%.	8	SCIENTIFIC COMMUNITY	Month 24
69	Publication a collaborative paper with with Spanish Association of Human Milk Banks	8	SCIENTIFIC COMMUNITY	Month 24
70	Publication of the new guidelines (objective 8.5)	8	SCIENTIFIC COMMUNITY	Month 24
71	Publication about new procedures and technology (objective 8.5)	8	SCIENTIFIC COMMUNITY	Month 24
72	Development of digital APP for mothers and specific material for workshops	8	SOCIETY	Month 12
73	Creation of a data-base: Registration in nationally representative cohorts of the prevalence of overweight, obesity, energy-balance related behaviours (EBRB) such as sedentary lifestyles, physical activity, dietary and sleep patterns together with social demographics (vulnerability) and different obstetric and perinatal factors that may predict the onset of excess weight and cardiometabolic disease throughout life. These data may be used in a recent future for bigger data analyses (BIG-DATA)	9	SCIENTIFIC COMMUNITY	January 2022-December 2023
74	Validated algorithm screening for the identification of individuals at cardiovascular risk from early stages of life in primary care.	9	SCIENTIFIC COMMUNITY	September 2022-June 2023
75	Recommendations and guidelines for the implementation of community intervention programmes* for the prevention and treatment of cardiometabolic risk and obesity early in life from primary care.	9	POLICY MAKERS	September 2022-June 2023
76	Guidelines and recommendations for public health practicioners for the promotion from primary care of cardiovascular health in children and adults, as well as the prevention and treatment of obesity and its comorbidities.	9	POLICY MAKERS	January 2024-December 2024
77	e-Health Assessment tool for the identification of nutritional and physical activity that may help to better understand what is the real situation and motivation of children early ages and how can be objectively monitoring them	9	SOCIETY	September 2022-June 2023
78	e-Health Assessment tool for the surveillance of dietary and physical interventions for prevention of cardiovascular diseases in children	9	SCIENTIFIC COMMUNITY	January 2024-June 2024

79	Report of the long-term follow up of multicenter study of cardiac arrest in children (PACHIN)	10	SCIENTIFIC COMMUNITY	Month 36
80	Report of national registry of pediatric stroke in children	10	SCIENTIFIC COMMUNITY	Month 18-36
81	Report of the multicenter prospective observational registry of high-risk congenital heart disease, cardiac surgery, esophageal or diaphragmatic surgery and children treated with extracorporeal membrane oxygenation (ECMO) therapy	10	SCIENTIFIC COMMUNITY	Month 18-36
82	Report of multicenter registry of rare genetic and metabolic disease in children	10	SCIENTIFIC COMMUNITY	Month 18-36
83	Clinical guidelines for prevention, early detection and follow-up of chronic serious diseases children (diabetes, chronic renal failure, celiac disease, prematurity	10	POLICY MAKERS	Month 20
84	Guidelines for nutritional and health monitoring of children with severe neurological diseases, esophageal atresia and congenital diaphragmatic hernia	10	POLICY MAKERS	Month 20
85	Nutritional protocol for the treatment of children with severe epilepsy	10	SCIENTIFIC COMMUNITY	Month 24
86	Report of the results of education activities of health care education	10	SOCIETY	Month 36
87	Recommendations of education activities of health care education in high risk children and families	10	SOCIETY	Month 20
88	Report of the evaluation of the Primary Care and Hospital Care Coordinated Program in technology dependent children	10	SCIENTIFIC COMMUNITY	Month 18-36
89	Report of the evaluation of technologies of telemonitoring and teleconsulting in technology dependent children with chronic serious disease children	10	SCIENTIFIC COMMUNITY	Month 18-36
90	Report of the evaluation of the program telemonitoring and medical teleconsultation in technology dependent children	10	SCIENTIFIC COMMUNITY	Month 18-36
91	Report of recommendations of ethical issues in chronic serious diseases in children on a home care program	10	SOCIETY	Month 24
92	Report through a publication environmental factor influencing the evolution of celiac pathology	11	SOCIETY	Month 24
93	Nutritional protocols for the treatment of celiac patients in primary care officesand in school canteens	11	SOCIETY	Month 24
94	Report through a publication the influence of pregnancy factors on food allergy development	11	SCIENTIFIC COMMUNITY	Month 36
95	Report through a publication new parameters involved in the development and evolution of food allergies	11	SCIENTIFIC COMMUNITY	Month 24
96	Report through a publication new biochemical parameters useful for the diagnosis and following up of chronic kidney disease	11	SCIENTIFIC COMMUNITY	Month 24
97	Clinical guide / publication describing criteria for early diagnosis of renal chronic patients at risk of neurological comorbidities	11	SCIENTIFIC COMMUNITY	Month 36

98	Clinical guide / publication describing criteria for early diagnosis of renal chronic patients at risk of cardiovascular comorbidities	11	SCIENTIFIC COMMUNITY	Month 36
99	End-users' survey (SO.1)	12	SOCIETY	Month 12
100	1 Focus group with parents (SO.1); 1 Focus group with children (SO.1); 1 Focus group with healthcare professionals (SO.1) and 40 Semi-structured interviews with parents (SO.1)	12	SOCIETY	Month 18
101	2 Workshops with children to assess their perceptions and understandings of shared decision-making and ethnically approaches in primary healthcare services (2x10 children) (SO.1)	12	SOCIETY	Month 20
102	Report on parents' and children's perceptions of gender, shared decision-making and ethnically approaches in primary healthcare services (SO.1)	12	POLICY MAKERS	Month 24
103	Academic article manuscript (SO.1)	12	SCIENTIFIC COMMUNITY	Month 32
104	Infographics to inform healthcare professionals about parents and children perceptions (SO.1)	12	SCIENTIFIC COMMUNITY	Month 24
105	2 Short videos (aprox. 6 min) to disseminate research results to parents and children (SO.1)	12	SOCIETY	Month 24
106	Report on maternal and infant healthcare professionals' perceptions of gender, shared decision-making and ethnically approaches in primary healthcare services Healthcare professionals' survey (SO.2)	12	POLICY MAKERS	Month 12
107	Report on participant observation in primary healthcare services	12	POLICY MAKERS	Month 18
108	30 Semi-structured interviews with healthcare professionals	12	SCIENTIFIC COMMUNITY	Month 18
109	Academic article manuscript	12	SCIENTIFIC COMMUNITY	Month 34
110	Short video (6 min. aprox.) to transfer research results to healthcare professionals	12	SCIENTIFIC COMMUNITY	Month 24
111	Best practice guide about gender and ethnic equality perspectives in healthcare	12	POLICY MAKERS	Month 30
112	3 Workshops for healthcare professionals (aprox. 3x15 participants):	12	SCIENTIFIC COMMUNITY	Month 30
113	Best practice guide about shared decision-making perspectives in healthcare	12	POLICY MAKERS	Month 30
114	Assessment report of current digital tools	12	SCIENTIFIC COMMUNITY	Month 24
115	App for monitoring maternal and infant health and wellbeing	12	SOCIETY	Month 36
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RICORS Code	RICORS Leader:
RD21/0012/0001	Elisa Llurba Olivé

LIST OF MILESTONES

MILESTONE Nº	MILESTONE NAME	WP Nº	DUE DATE	MEANS OF VERIFICATION
1	Harmonization of interdisciplinary research activity with primary care services at first trimester of pregnancy	1	Month 3	Standard operative procedure
2	Training/education of study personnel and quality control	1	Month 3	Educational activity
3	Database and biobanck for the storage of data and samples derived from the study	1	Month 3	Database and Biobanck
4	Serum nutritional biomarkers determinations during pregnancy	1	Month 30	Scientific and technical report
5	Breastmilk analysis	1	Month 30	Scientific and technical report
6	Data analysis: The third year of the project will be mainly dedicated to completing follow-up and data analysis. Conventional statistics will be combined with advanced methods and machine learning, supported by data scientists to identify complex relationships	1	Month 30	Peer reviewed scientific papers
7	Dissemination: the last 3 months will be committed to scientific reports, publications and dissemination of results to the scientific community and society	1	Month 30	Guidelines and Recommendations for public health practitioners
8	Data management: kick-off and follow-up meetings will take place	2	Monthly	Scientific and technical reports
9	To set the protocols and SOP for all the procedures and determinations	2	Month 3	Scientific and technical reports
10	To set the framework for sample biobank within the network	2	Month 6	Scientific and technical reports
11	Validation of first trimestre contingent screening of PE to be used in primary care setting in first 400 patients included in the study	2	Month 12	Scientific and technical reports
12	Validation of diagnostic tools - angiogenic factors near term- that will allow selection of high-risk pregnancies and individualized management	2	Month 12	Peer reviewed scientific papers
13	Analysis of experiences validation survey	2	Month 12	Peer reviewed scientific papers
14	Elaboration of information and recommendation materials for pregnant women, based on women's desires and feelings related to their experiences	2	Month 18	Information material for pregnant women
15	Cost-effectiveness analysis	2	Month 30	Peer reviewed scientific papers
16	Data analysis: The third year of the project will be mainly dedicated to completing follow-up and data analysis. Conventional statistics will be combined with advanced methods and machine learning, supported by data scientists to identify complex relationships	2	Month 30	Scientific and technical reports
17	Dissemination: the last 3 months will be committed to scientific reports, publications and dissemination of results to the scientific community and society	2	Month 36	Guidelines and Recommendations for public health practitioners

18	Data management: kick-off and follow-up meetings will take place	3	Monthly	Scientific and technical reports
19	To set the protocols and SOP for all the procedures and determinations	3	Month 3	Standard operating procedure
20	To set a sample biobank within the network	3	Month 6	Database and Biobank
21	To analyze angiogenic factors and CV disease variables in subsequent development of CV complications in women after an episode of placental insufficiency	3	Month 12	Peer reviewed scientific papers
22	To establish biophysical and biochemical biomarkers for CV risk after pregnancy complicated with PE	3	Month 12	Peer reviewed scientific papers
23	Cardiac dysfunction and metabolic status at 12 months after delivery and its correlation with cardiac and PE risk variables obtained during pregnancy	3	Month 24	Peer reviewed scientific papers
24	A CV score for women that developed PE during pregnancy for early detection of CV risk factors	3	Month 24	Patent for a new predictive tools
25	Analysis of Health-Promoting Lifestyle Profile and WHOQOL-BREF questionnaire in the study groups	3	Month 24	Peer reviewed scientific papers
26	Development of CV risk app	3	Month 24	Scientific and technical reports
27	Validation of app	3	Month 30	Patent for e-health tool
28	Data analysis: The third year of the project will be mainly dedicated to completing follow-up and data analysis. Conventional statistics will be combined with advanced methods and machine learning, supported by data scientists to identify complex relationships	3	Month 30	Peer reviewed scientific papers
29	Dissemination: the last 3 months will be committed to scientific reports, publications and dissemination of results to the scientific community and society	3	Month 36	Guidelines and Recommendations for public health practitioners
30	Data management: kick-off and follow-up meetings will take place	4	Monthly	Scientific and technical reports
31	To set the protocols and SOP for all the procedures and determinations	4	Month 3	Scientific and technical reports
32	To set a data base and a sample biobank within the network	4	Month 6	Database and Biobank
33	Prospective follow-up and integration data of the maternal exposure to community-level and individual-level environmental risk factors and lifestyle risk factors from the prenatal period to early childhood	4	Month 36	Peer reviewed scientific papers
34	Biobank of samples from pregnant women, cord blood and placenta for ulterior studies on environmental exposure during pregnancy	4	Month 36	Biobank
35	Clinical guidelines and recommendations for the early detection and prevention of community-level and individual-level environmental risk factors during pregnancy	4	Month 36	Guidelines and Recommendations for public health practitioners
36	Clinical guidelines and recommendations for the early detection and prevention of lifestyle risk factors during pregnancy	4	Month 36	Guidelines and Recommendations for public health practitioners

37	Recommendations of an integrated and coordinated Primary Care and hospital program to follow-up infants with a higher risk of worse neurodevelopment, obesity, and cardiometabolic syndrome risk factors	4	Month 36	Guidelines and Recommendations for public health practitioners
38	Data about to the prevalence of exposure to substances of abuse during pregnancy in 2 cohorts	5	Month 24	Scientific and technical reports
39	Webinar about environmental contaminants and consumption of substances of abuse during pregnancy	5	Month 24	Dissemination activity
40	Guidelines about environmental contaminants and consumption of substances of abuse during pregnancy	5	Month 24	Guidelines and Recommendations for public health practitioners
41	Preventive strategies about prenatal and postnatal exposures to substances of abuse	5	Month 36	Peer reviewed scientific papers
42	Intervention strategies about prenatal and postnatal exposure to substances of abuse	5	Month 30	Peer reviewed scientific papers
43	Strategies for children prenatally exposed to substances of abuse (children with FASD)	5	Month 18	Peer reviewed scientific papers
44	The development of program about mental health problems of high complexity	5	Month 30	Peer reviewed scientific papers
45	A model of maternal and child environmental health program and a model of intervention unit about maternal and child environmental health	5	Month 36	Peer reviewed scientific papers
46	To establish a Follow Up Flow Diagram to identify, recruit, follow and minimize losses of Late Preterm Infants born at the referral centers participating in this program	6	Month 1	Standard operator procedure
47	To provide Online Follow Up Course and Training Program for health care personnel of Primary Care Centers. This online course is a training initiative of the SENeo in Neurodevelopment. It integrates professionals trained and specialized in assorted areas for the multidisciplinary assessment of the child. The program provides specific knowledge and tools for the assessment of the preterm child and for the early identification of warning signs	6	Month 3	Educational material for professionals
48	To design an Electronic Data Register Program to retrieve and analyze data from all recruited patients	6	Month 2	Data base
49	Evaluation of the degree of fulfillment of the Program	6	Month 6	Scientific and technical reports
50	To perform a statistical analysis of neurodevelopmental milestones, sleeping and eating habits and anthropometry looking for early predictive biomarkers of neurodevelopmental outcome at school age.	6	Month 34	Scientific and technical reports
51	Data analysis: The third year of the project will be mainly dedicated to completing follow-up and data analysis. Conventional statistics will be combined with advanced methods and machine learning, supported by data scientists to identify complex relationships	6	Month 30	Scientific and technical reports
52	To write a consensus guideline for the Follow Up of Late Preterm infants that include early predictive biomarkers applicable in the Primary Health Care Centers and sent to the Spanish Neonatal Society, Spanish Pediatric Association and Spanish Neonatal Nursing Society for approval	6	Month 36	Guidelines and Recommendations for public health practitioners

53	Publication and a guide if the procedure used is a reliable model capable of predicting early the presence of compromised blood flow to the organs (brain and intestine), and evaluation of the injury and its multidisciplinary follow-up in hospital and in Primary Care after discharge	7	Month 30	Scientific and technical reports
54	Evaluation of the keys to obtain a better predictive value of neuroimaging (US, MRI) and EEG as validate biomarkers of brain damage	7	Month 12	Scientific and technical reports
55	Evaluation of the Clinical guide / publication for the adequate management of newborns in the NICU with cardiovascular instability	7	Month 24	Guidelines and Recommendations for public health practitioners
56	Evaluation of the action for multidisciplinary prevention, early detection and follow-up with special attention to the involvement of Primary Care	7	Month 30	Scientific and technical reports
57	Evaluation of the Clinical guidelines for a multidisciplinary hospital follow-up calendar and Primary Care of the newborn with risk of neurodevelopment impairment	7	Month 20	Guidelines and Recommendations for public health practitioners
58	To carry out a baseline analysis of current procedures for neonatal care in the participant NICUs in order to identify the needs, wishes and requirements of all stakeholders involved in neonatal care	7	Month 12	Scientific and technical reports
59	Evaluation of the FiCare implementation according to the specificities of each context: commitment levels (basic / advanced), procedures, training methodology and materials, evaluation framework for the overall project's approach, so all data will be comparable between sites	7	Month 30	Scientific and technical report
60	Verification of the necessary arrangements to achieve the approval from the corresponding research ethics committees in each site will be made	7	Month 6	Scientific and technical reports
61	To assess the overall impact of FIcare model -from the clinical, social, economic, psychological and cultural point of view- on infants' health, parents and healthcare professionals to extract conclusions of the benefits of implementing FICare program independent of the context or level of NICU care and points for improvement (gender and equality issues will be specifically addressed). A value of implementation analysis of the model will be performed, which will be decisive to inform decision makers	7	Month 30	Peer reviewed scientific papers
62	At least 2D or 3D BFHI-UNICEF Phase accreditation for Primary Care centers	8	Month 36	Acreditation
63	Related to accreditation phase, results of the validated annual surveys about breastfeeding rates from both Hospitals and Primary Care centers	8	Month 12	Scientific and technical reports
64	Development of digital APP to enhance survey's distribution	8	Month 24	Patent for e-health tool.
65	Collaborative papers with IHAN UNicef about the accreditation experience of the Primary Care centers	8	Month 36	Peer reviewed scientific papers
66	Development of digital APP for professionals and mothers that includes support content about human milk expression and storage in NICUs	8	Month 24	Patent for e-health tool.

67	Accreditation by Regional Human Milk Banks of new NICUs to collect donor milk for admitted newborn infants	8	Month 24	Accreditation
68	Specific material will be developed for workshops for mothers and professionals	8	Month 12	Information material
69	Protocols for selecting and recruiting donors and human milk collection in Primary Care centers	8	Month 12	Standard operating procedure
70	Certification by Regional Human Milk Banks of Primary Care centers to recruit and select donors and to collect and store human milk	8	Month 24	Certification
71	Publication collaborative scientific papers with Spanish Association of Human Milk Banks about the experience of including Primary Care centers in the human milk bank network	8	Month 36	Peer reviewed scientific papers
72	Guidelines of standard procedures to process donor milk and elaborate special preparations with human milk for sick infants (defatted milk, high protein milk, etc.)	8	Month 36	Standard operating procedure
73	Utility model or patent for developed technologies	8	Month 36	Patent for e-health tool.
74	Publication of scientific papers about the guidelines and the new procedures and technologies developed	8	Month 36	Peer reviewed scientific papers
75	Development of digital APP for mothers that includes support content to facilitate human milk expression and storage after returning to work and information to improve the safety of the process	8	Month 12	Patent for e-health tool.
76	Specific material will be developed for workshops for mothers	8	Month 12	Information material
77	Data management: kick-off and follow-up meetings will take place	9	Monthly	Scientific and technical reports
78	To set the protocols and SOP for all the procedures and determinations	9	Month 3	Scientific and technical reports
79	Registry of the whole perinatal period health for the mother-child binomial to be used both in recent and later analyses or studies	9	Monthly	data base
80	Summary of data on the best tools to be used for screening and for interventions on EBRBs	9	Month 24	Peer reviewed scientific papers
81	Development of CV risk and surveillance app for children at risk	9	Month 24	Scientific and technical reports
82	Validation of app	9	Month 30	Patent for e-health tool.
83	Data analysis: The third year of the project will be mainly dedicated to completing follow-up and data analysis. Conventional statistics will be combined with advanced methods and machine learning, supported by data scientists to identify complex relationships	9	Month 30	Peer reviewed scientific papers

RICORS Code	RICORS Leader:

LIST OF PROGRESS INDICATORS

	PROGRESS INDICATORS			
OBJECTIVE CODE	CODE	DEFINITION AND MEASUREMENT	VALUE	DUE DATE
1	**1**	Measurements of serum-breast milk nutritional biomarkers during pregnancy and association with the maternal dietary information recorded from several cohorts from pregnancy to improve the nutrition during pregnancy	Date-base and statistical analysis	Month 24
	2	Evaluation of dietary habits of GDM mothers postpartum as well as duration of breastfeeding in follow up pregnancy cohorts	Scientific peer review paper	Month 24
	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36
2	**1**	Report on maternal feelings and experiences from these interventions	Scientific peer review paper	Moth 12
	2	Validation of diagnostic tools - angiogenic factors near term- that will allow selection of high-risk pregnancies and individualized management	Internal progress report and Peer reviewed scientific papers	Moth 12
	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36
3	**1**	Analyze angiogenic factors and CV disease variables	Peer reviewed scientific papers	Month 12
	2	Analysis of Health-Promoting Lifestyle Profile and WHOQOL-BREF questionnaire in the study groups	Peer reviewed scientific papers	Month 24
	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36
4	1	Assessment of exposure to air pollutants, greens and noise in a cohort of 1200 healthy pregnant women with singleton pregnancy	Internal progress report and Peer reviewed scientific papers	Month 24
	2	Analysis of perinatal results of the cohort of a randomized controlled trial (IMPACT BCN: Improving Mothers for a better PrenAtal Care Trial BarCeloNa) of 1221 singleton pregnancies. Women were randomized following a 1:1:1 ratio to one of three arms of intervention: i) Mediterranean diet; ii) Mindfulness Based Stress Reduction program; iii) usual care without any intervention.	Internal progress report and Peer reviewed scientific papers	Month 24

	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36
5	1	Determine the prevalence of exposure to substances of abuse (i.e., alcohol, cannabis, other drugs of abuse) during pregnancy in different biological matrices (neonatal meconium, maternal hair, breast milk	Internal progress report and Peer reviewed scientific papers	Month 24
	2	Determination of follow up strategies for children prenatally exposed to substances of abuse	Internal progress report and Peer reviewed scientific papers	Month 24
	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36
6	1	Late-preterm data registry to store all the clinical and analytical data related to the patients' evolving during the first 24 months after birth	Internal progress report and Peer reviewed scientific papers	Month 24
	2	Follow Up Program strategy for Late Preterm Infants (>34 to 36+6 weeks of gestation) for early detect neurodevelopmental and sensorial deficits.	Internal progress report and Peer reviewed scientific papers	Moth 18
	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36
7	1	Registry of risk factors associated with neurodevelopmental disorders in children at risk	Internal progress report and Peer reviewed scientific papers	Moth 18
	2	Program of care continuity from admission and after discharge to guarantee comprehensive multidisciplinary care with the participation of Primary Care, of all neonates at risk of adverse neurodevelopment	Internal progress report and Peer reviewed scientific papers	Moth 30
	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36
8	1	Baby-friendly Hospital Initiative (BFHI)-UNICEF accreditation of the participation centers	Acreditation	Month 6
	2	Inclusion of centers in the milk bank network	Internal progress report	Month 24
	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36

9	1	National registry of representative cohorts of the prevalence of overweight, obesity, energy-balance related behaviours (EBRB) such as sedentary lifestyles, physical activity, dietary and sleep patterns together with social demographics (vulnerability) and different obstetric and perinatal factors that may predict the onset of excess weight and cardiometabolic disease throughout life	Internal progress report	Month 24
	2	Validated algorithm screening for the identification of individuals at cardiovascular risk from early stages of life in primary care.	Internal progress report and Peer reviewed scientific papers	Moth 30
	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36
10	1	Multicenter prospective observational registry with long-term follow up of risk factors for neurologic disability after serious disseasses in children.	Internal progress report	Month 24
	2	Development of an integrated and coordinated follow-up program including Hospital and Primary Care services to technology dependent children (respiratory assistance, artificial nutrition, high risk children of cardiac arrest)	Internal progress report and Peer reviewed scientific papers	Moth 30
	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36
11	1	Description of parameters involved in the development and evolution of food allergies	Internal progress report and Peer reviewed scientific papers	Moth 30
	2	Description of new biochemical parameters useful for the identification of vulnerable children at risk of severe chronic renal disease	Internal progress report and Peer reviewed scientific papers	Moth 30
	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36
12	1	Infographics to inform healthcare professionals about parents and children perceptions	Dissemination	Month 12
	2	Report on maternal and infant healthcare professionals' perceptions of gender, shared decision-making and ethnically approaches in primary healthcare services Healthcare professionals' survey	Dissemination	Month 12
	3	Translation to mothers and children through implementation of the findings in primary care settings.	Implementation	Month 36

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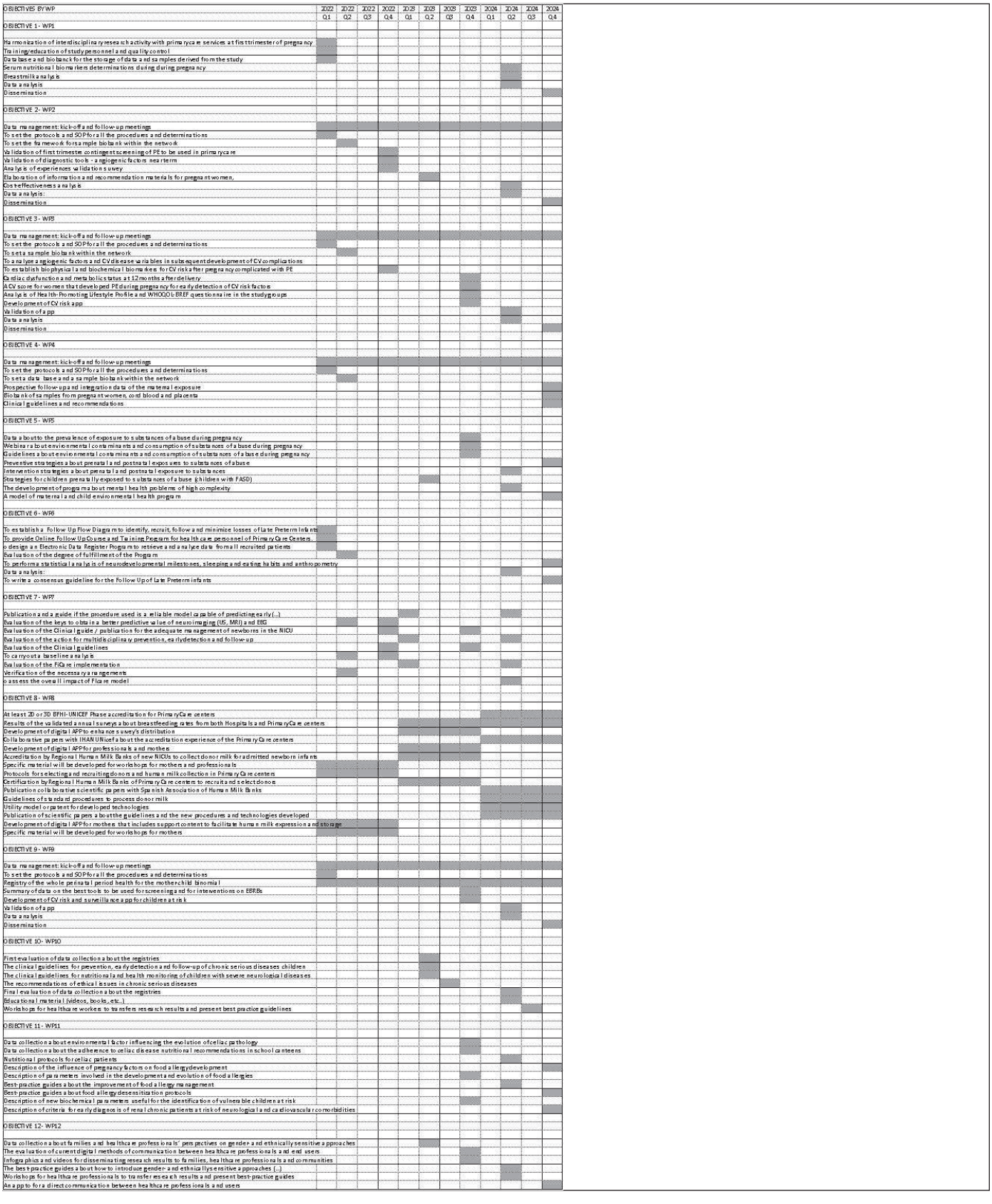
SCHEDULE / TIMELINE

Please provide a diagram

Max. 1 figure (jpg format)



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DATA MANAGEMENT PLAN

Please provide a brief description of the Data Management Plan (DMP) regarding data collected or generated within the framework of the RICORS activity project. Max. 1 page

A detailed Data Management Plan will be created at the beginning of the project (months 1-3). Here we describe the principles of this plan:

TYPE AND FORMAT OF DATA TO BE COLLECTED/GENERATED

The rules for processing of personal data, as required by the European Directive 95/46/EC will be followed. According to this directive, the coordinator of the project is defined here as controller of data. The following principles will be observed:

- Legitimate acquisition and processing: The information recorded will be relevant and not excessive. The data will be processed only for the purposes defined in each of the studies planned within the consortium. Unambiguous written consent will be obtained by the data subject.
- The Informed Consent text include clear information about of each of the studies planned within the consortium. It will be made completely and unambiguously clear that women/parents/children are free to refuse to participate in all or any aspect of the studies, at any time and for any reason.
- Personal Data will be encrypted through a process in order to guarantee anonymity. The identity of the data subjects will be kept only at a local level.

PROCEDURE TO ACCESS DATA

- Data will be managed using Clinapsis (www.clinapsis.com), an application designed to manage clinical studies ensuring the accuracy and traceability of the data and in full compliance with the provisions of Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the guarantee of digital rights. The electronic records will be only accessible to members of the research team with limited access through username and password of authorized personnel. Data will be accessed only for statistical processing by professional statisticians with no access to the personal information of the study subjects.
- The data collected will not be transferred or interchanged with other institutions.

DATA OWNERSHIP

- Exploitation/dissemination/protection activities will be discussed and agreed among the participating researchers involved in jointly generated knowledge.
- We will ensure the consortium results to be disseminated as swiftly as possible as open access to scientific publications.

REPOSITORY TO DEPOSIT DATA

- The Findable, Accessible, Interoperable and Reusable (FAIR) principles will be applied. Metadata standards and vocabularies will be associated to the data, traceable identifiers will be used, and storage and repository mechanisms will be planned.
- The investigators agree to archive and/or arrange for secure storage of Clinical Trial materials and records for a minimum of 5 years after the close of the trial. Essential traceability documentation will be archived for a minimum of 30 years from the expiry date in accordance with Regulation 1394/2007 and the applicable Directives therein.
- The results of the studies proposed in this proposal will be disseminated regardless of the direction of effect.
- Each of the studies planned within the consortium will be disseminated via scientific publications (open access), scientific meetings, press and social media. All will include the project logo and prominently acknowledge the grant agreement number.
- All publications and data generated by the project will be uploaded to open acces Digital repository.

PROCEDURE PLANNED TO GUARANTEE THE SPECIFIC ETHIC AND LEGAL REQUERIMENTS

The coordinator shall implement the research project in full respect of the legal and ethical national requirements and code of practice:

- Creation of a specific Data Management Plan and a Statistical Plan Analysis at the beginning of the project (months 1-3)
- The coordinator and PI of this project will be responsible for scientific coordination of the trial, communications within the centers, coordinating payments, reports and dissemination. A project manager will be hired to support project's management and communication among the participant centers.
- Researchers will receive specific training following the Good Clinical Practice principles.

An external Data and Safety Monitoring Board will be selected in order to evaluate ethical issues relating to any adverse events of each of the studies planned within the consortium.

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AVAILABLE RESOURCES

Indicate the available resources to carry out the programme including infrastructures, equipment and other shared resources.

Max. 2 pages (10,700 characters)

1. Human resources: The participating groups and centers have the entire required investigators necessary to carry out the studies within the Network. The multidisciplinary teams includes physicians, midwifes, biologists, nurses, psychologists and a dedicated management-administration team, with dedicated areas both at terciary and primary care settings, with offices for researchers and laboratories for processing and analyzing human samples.

2. Web Page of the RICORS NETWORK that will allow to upload to specific links data coming from patients, imaging, electrophysiology and results of analysis. The Manager of the Network is working on the implementation of the web page, and a substantial investment is being done to facilitate the Coordinator and the Sub-coordinators input of data coming from the different groups of the Network.

3. General resources of the NETWORK

The complete resources are described in the web page at www3.redsamid.net

All centers participating in the Network have: 2.1. Access to Biobank; 2.2. Specific protocols to sample, process and storing biological material until stored in the Biobank (e.g. samples retrieved during the week ends or nights); 2.3. Centrifuges; 2.4. Ultrafreezers; 2.5. Fungible material to collect samples; 2.6. Shipment facilities (dry ice, boxes, couriers)

4. Obstetric, Neonatal and Infant Services of the NETWORK

All the centers participating in the RICORs have resources to effectively control and monitor pregnancy (Ultrasound; Doppler; etc.)

Delivery room facilities with updated installations to adequately perform resuscitation following updated protocols, retrieve information from the newborn (pulse oximetry, respiratory function, basic biochemical analysis) and sampling of biomaterial for further analysis.

Obstetric and Neonatal and Pediatric Intensive Care Units endowed with updated monitoring and therapeutic systems.

5. Metabolomic platforms for target and untarget metabolomics in biofluids and tissues

Mass spectometry triple quadrupole analyzers (QqQ): UPLC-QqQ, WatersAcquity-Xevo TQ-S

Mass spectrometry quadrupole-time of flight analyzed (QToF): UPLC-QToF, WatersAcquity-Synapt

Mass spectrometry triple quadrupole (QqQ): UPLC-QqQ, Agilent 6460 y HPLC-QqQ, Waters 2795XL-QuattroMicro

Mass spectrometry triple quadrupole time of flight analyzers (QToF): HPLC-QToF, Agilent 1100, ABSciex QSTAR Elite y GC-QToF, Agilent 7200

Liquid Chromatography Agilent 2695, with UV-VIS detection (Agilent DAD 2996) or fluorescence detection (Shimadzu RF535)

6. Genomic and epigenomic platforms

Among the various groups we have access so platforms related with genomic and epigenomic diagnosis

1. Assessment of the quality of nucleic acids (Determination of the concentration and contaminants of nucleic acids (RNA/DNA); Electrophoresis)

2. Arrays: Genotyping and gene expression using arrays; Analysis of the results of personlized arrays Illumina platform; Global profiles of DNA methylation using arraygs in platform ISCAN (Illumina; 450K; Epic DNA methylation beadchip)

3. Sequencing: Conventional or Sanger sequencing; Massive sequencing; Studies on the validation of DNA methylation using pyrosequencing.

4. Polymerase chain reaction (Conventional PCR; Qualitative PCR)

5. Immunoprecipiation (Studies of the global profile of histone modification or of transcription factors combining immunoprecipitation of chromatin and Next Generation Sequencing; Studies on the transcriptomic profie in real time using RNApol-ChIP-seq technique).

To perform these processing we have access to the following devices

- Spectrophotometer NanoDrop 2000c Thermo Scientific
- Qubit Invitrogen fluorimeter
- Qiaxcel Qiagen t Bioanalyzer 2100 Agilent
- GeneChip® Scanner 3000 7G System Affymetrix
-ViiA7 of Applied Biosystems
-Sequencing ABI Prism 3500 of Applied Biosystems
- Sequencing 454 GS Junior of Roche

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IMPACT AND DISSEMINATION

Please summarize the programme and expected results in the population, using a non-scientific language understandable to the general public. Describe:
- General characteristics of the programme, specially those related to relevance and vulnerability of patient´s health outcomes approached within the thematic area.
- Expected impact of the programme results, in terms of improve capacity in healthcare procedures towards an improvement of patients' health and life quality.
- Dissemination plan targeted to general population, planned actions aimed at segments of the population with special interest/ vulnerability within the thematic area.

Max. 1 pages (5,250 characters)

General characteristics of the programme, especially those related to relevance and vulnerability of patient´s health outcomes approached within the thematic area.

Children diseases and disabilities such as obesity, cardiovascular disease and impaired neurodevelopment have a lifelong effect on the productivity and quality of life of the affected person and impose a considerable burden on their families as well as the education, social security, and healthcare systems. The annual health care costs in Europe per child/adolescent with these disorders, has led to growing acknowledgement of the problem as a major public health concern. Even though estimates differ, there is increasing evidence that the prevalence of such conditions have been growing in the last years which provides an additional argument that innovative, feasible, and cost-effective approaches to tackle these issues are of highest urgency.

The whole the project focuses on a prevalent diseases such as preeclampsia, pretermaturity, impared neurodevelopment and cardiovascular diseases. All of these conditions have a great impact, affecting 3 in 10 adults and found in one of the priority lines of research AES and in perinatal medicine.

Expected impact of the programme results, in terms of improve capacity in healthcare procedures towards an improvement of patients' health and life quality.

The proposal is highly relevant: it addresses one of the main unsolved issues in maternal and pediatric medicine, i.e. prediction and prevention of long term sequele of perinatal complications both for the mother and for the newborn. The findings will have a high impact in the field.

The proposal is highly translational, because:

-it addresses a well-defined questions

-if positive, the results could be immediately applicable in the settings included in this proposal (primary care) and also in similar healthcare systems. Likewise, the solution here tested represents a pragmatic and simplified approach, which with minimal validation could be readily applicable in many healthcare settings worldwide.

-the secondary aims will provide highly valuable information on (1) the effects of pregnancy on women's cardiovascular health later in life, and (2) the cost-effectiveness and impact on maternal and children views on the emerging trend of implementing heath policies, potentially opening new research avenues on these fields.

Dissemination plan targeted to general population, planned actions aimed at segments of the population with special interest/vulnerability within the thematic area.

An effective dissemination strategy will ensure that the rationale behind the current proposal (and ultimately the results themselves) is rapidly understood by the wider community, increasing the likelihood of adoption and thus impact on the health of Spanish citizens. The dissemination efforts will be directed to all major stakeholders as general public and parents associations. We as a consortium have a special interest in involving parents and greater public in the research process, as well as the research community and other stakeholders.

The majority of strategies that are planned within the consortium to improve different maternal and children conditions include as derivable, information materials and digital dissemination in social networks. Moreover the inclusion of eHealth solutions are also within the scope of the consortium in order to empower women, parents and children in their on health.

Website: Our website will be the central source of information for women, parents, public in general as well as other researchers and stakeholders. In addition to general dissemination, a section of the website will also be developed to specifically engage target industry. The site will be updated frequently with information about the status of the project,

interesting news and stories, six monthly newsletters and publications generated by the project.

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EXPECTED IMPACTS SET OUT IN THE WORK PROGRAMME

Please bind each objective with its expected impact.

Programme:	PRIMARY CARE INTERVENTIONS TO PREVENT MATERNAL AND CHILD CHRONIC DISEASES OF PERINATAL AND DEVELOPMENTAL ORIGIN
OBJECTIVES INCLUDED	EXPECTED IMPACTS
To promote maternal health (nutrition and exercise) in obese and diabetic women to improve perinatal and infant outcomes.	Reduction of obesity and metabolic disorders in women that developed diabetes during pregnancy.
To identify women at risk for placental complications of pregnancy (preeclampsia and intrauterine growth restriction), implementing screening program and interventions in the first and third trimesters of pregnancy in primary care settings	Reduction of term and preterm preeclampsia by 50%
To improve cardiovascular and renal health in women by early identification of risk factors according to obstetrics outcomes, and to provide integral primary care follow-up	Reduction of cardiovascular and renal disease in women after preeclampsia.
To elucidate the role of environmental factors, green spaces and noise pollution in pregnancy outcomes at a community level.	To implement public health policies for the reduction of toxic environmental factors in the community level.
To early detection, community support and treatment of women that use or abuse drugs and alcohol during pregnancy, and family care support for mother-children to avoid long-term consequences of addictive behaviours	To increase the detection and treatment of women with addiction to abuse drugs and alcohol during pregnancy.
To early detect short-and-long-term neurocognitive, developmental and sensorial consequences of Late Prematurity.	To increase treatment of neurodevelopmental impairment in late-preterm children.
Identification of patients at risk to prevent or minimize neurodevelopmental disorders by implementing multidisciplinary measures in a hospital and primary care continuity program	To increase the detection of neurological disorders in children at risk
Improve the health of mother and child promoting breastfeeding and the use of human milk from birth up to the age of two.	To increase breastfeeding rate among mothers in the community up to age of two
To evaluate the impact of lifestyle strategies to improve cardiovascular and metabolic health in those children with high-risk (intrauterine growth restriction, maternal diabetes, obesity);	To reduce cardiovascular disease risk factors in children
To implement protocols to aid in prevention, early detection, monitoring and sequelae of childhood chronic serious diseases (cardiac arrest, paediatric stroke, brain trauma, post-cardiac surgery, neuro-infections, long-term hospital stay)	To improve quality of life and decrease co-morbidities and sequeale in children with chronic serious diseases
Identification of mechanisms that improve treatment and follow up of children chronic digestive and renal pathologies and to established new protocols for the identification of subjects at risk for the prevention of disease evolution from primary health care units.	To increase detection and treatment of children with digestive and renal pathologies

To include (a) patients' experiences and point of views in the design of policies to improve different aspects of maternal and children health and (b) include e-health technologies to improve detection and follow-up of different maternal and children chronic conditions, at the primary care level.	a) Acknowledgment of mothers, parents and children health needs. b) App for monitoring maternal and infant health and wellbeing.

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SUMMARY OF THE IMPACTS INDICATORS

IMPACT INDICATOR	EXPECTED TIME OF ACHIEVEMENT	EXPECTED OUTCOME
Guideline for diagnostic and management of women GDM from first trimester of pregnancy in primary care services	Month 36	Reduction of obesity and metabolic disorders in women that developed diabetes during pregnancy.
Validation of diagnostic tools - angiogenic factors near term- that will allow selection of high-risk pregnancies and individualized management	Month 12	Reduction of term and preterm preeclampsia by 50%
App for implementation of life-style interventions to improve quality of life after PE in young mothers	Month 36	Reduction of cardiovascular and renal disease in women after preeclampsia.
Clinical guidelines and recommendations for the early detection and prevention of community-level and individual-level environmental risk factors during pregnancy	Month 36	To implement public health policies for the reduction of toxic environmental factors in the community level.
Report on Preventive and intervention strategies about prenatal and postnatal exposures to substances of abuse	Month 36	To increase the detection and treatment of women with addiction to abuse drugs and alcohol during pregnancy.
Consensus guideline for the Follow Up of Late Preterm infants that include early predictive biomarkers applicable in the Primary Health Care Centers and sent to the Spanish Neonatal Society, Spanish Pediatric Association and Spanish Neonatal Nursing Society for approval	Month 36	To increase treatment of neurodevelopmental impairment in late-preterm children.
Clinical guidelines for a multidisciplinary hospital follow-up calendar and Primary Care of the newborn with risk of neurodevelopment impairment	Month 30	To increase the detection of neurological disorders in children at risk
Development of digital APP for mothers that includes support content to facilitate human milk expression and storage after returning to work and information to improve the safety of the process	Month 12	To increase breastfeeding rate among mothers in the community up to age of two
e-Health Assessment tool for the surveillance of dietary and physical interventions for prevention of cardiovascular diseases in children	Month 18	To reduce cardiovascular disease risk factors in children
Workshops for healthcare workers to transfers research results and present best practice guidelines	Month 32	To improve quality of life and decrease co-morbidities and sequeale in children with chronic serious diseases
Clinical guide / publication describing criteria for early diagnosis of digestive and renal chronic patients at risk of cardiovascular comorbidities	Month 36	To increase detection and treatment of children with digestive and renal pathologies

a-The best-practice guides about how to introduce gender- and ethnically sensitive approaches and shared decision-making, designed in a collaborative process with families b-Assessment report of current digital tools of communication between healthcare professionals and end users	a-Month 30 b-Month 24	a- Acknowledgment of mothers, parents and children health needs. b-App for monitoring maternal and infant health and wellbeing.

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COMMUNICATION PLAN OVERVIEW

Describe the proposed communication activities for promoting the programme and its findings.

Programme: PRIMARY CARE INTERVENTIONS TO PREVENT MATERNAL AND CHILD CHRONIC DISEASES OF PERINATAL AND DEVELOPMENTAL ORIGIN

STAKEHOLDERS OR TARGET GROUPS	ACTIVITY OR CHANNEL	PURPOSE	PARTNERS/GROUPS
Midwifes and mothers, primary care obstetricians. Barcelona Heath Hub, Mediktor, BBraun, Ferring, Ordesa, ROCHE	Webmail, webinar, video, social media, SEGO, FIGO, SCOG	Guideline for diagnostic and management of women GDM from first trimester of pregnancy in primary care services	Larqué -RD21/0012/0002 Rodríguez- RD21/0012/0012 Llurba - RD21/0012/0001 Gómez -RD21/0012/0003 García - RD21/0012/0017 Mesa - RD21/0012/0008
Midwifes and primary care obstetricians. Barcelona Heath Hub, Mediktor, BBraun, Ferring, Ordesa, ROCHE	Webmail, webinar , SEGO, FIGO, SCOG, ROCHE diagnostics, Thermofisher	Clinical guidelines for prediction and prevention of PE and other complications of pregnancy such as IUGR, prematurity and neonatal complications	Llurba - RD21/0012/0001, Boronat – RD21/0012/0015, Cabañas – RD21/0012/0014, Gómez -RD21/0012/0003 García - RD21/0012/0017 CA3 Rodríguez- RD21/0012/0012, Larqué -RD21/0012/0002; Loureiro – RD21/0012/0006, CA10 CA11 Marre – RD21/0012/0018
Midwifes and mothers Barcelona Heath Hub, Mediktor, BBraun, Ferring, Ordesa, ROCHE	Webmail, webinar, video, social media	Information material and recommendations for pregnant women relative to PE, prediction and prevention strategies and its consequences	Llurba - RD21/0012/0001, Boronat – RD21/0012/0015, Cabañas – RD21/0012/0014, Gómez -RD21/0012/0003 García - RD21/0012/0017 CA3 Rodríguez- RD21/0012/0012, Larqué -RD21/0012/0002; Loureiro – RD21/0012/0006, CA10 CA11 Marre – RD21/0012/0018
Primary care practitioners, cardiologist, nefrologists. Barcelona Heath Hub, Mediktor, BBraun, Ferring, Ordesa, ROCHE	SEH-LELHA (Sociedad Española de Hipertensión) SEN (Sociedad Española de Nefrología)	Clinical guidelines and recommendations for prediction and prevention of CV disease in women that developed PE	Fernádez- RD21/0012/0019, Llurba - RD21/0012/0001, Gómez -RD21/0012/0003 García - RD21/0012/0017 Marre – RD21/0012/0018 Herraiz – RD21/0012/0024 Larqué -RD21/0012/0002
Primary care practitioners, Midwifes and mothers Barcelona Heath Hub, Mediktor, BBraun, Ferring, Ordesa, ROCHE	SEGO, FIGO, SCOG	Infographics and short videos on recommendations for young women relative to PE and CV disease, prediction and prevention strategies and its consequences	Fernádez- RD21/0012/0019, Llurba - RD21/0012/0001, Gómez -RD21/0012/0003 García - RD21/0012/0017 Marre – RD21/0012/0018 Herraiz – RD21/0012/0024 Larqué -RD21/0012/0002

STAKEHOLDERS OR TARGET GROUPS	ACTIVITY OR CHANNEL	PURPOSE	PARTNERS/GROUPS
Public health politicians, Non-governmental agencies, OMS, European Authorities	Webmail, webinar, video, social media, (Asociación Española de Pediatría) AEPap (Asociación Española de Pediatría de Atención Primaria) SENeo (Sociedad Española de Neonatología)	Clinical guidelines and recommendations for the early detection and prevention of community-level and individual-level environmental risk factors during pregnancy	Gómez -RD21/0012/0003 García - RD21/0012/0017 Llurba - RD21/0012/0001, Pallás – RD21/0012/0009, Rodríguez- RD21/0012/0012 Larqué -RD21/0012/0002 Cabañas – RD21/0012/0014
Pediatricians, Obstetricians, midwifes, Primary care practitioners, and mothers	Webmail, webinar, video SEGO, FIGO, SCOG, SENeo, AEPap, EAP,	-Guidelenes on preventive strategies of prenatal and postnatal exposures to substances of abuse -specific guidelines for professionals and families about FASD	García - RD21/0012/0017 Gómez-RD21/0012/0003 Boronat – RD21/0012/0015, Pallás – RD21/0012/0009 Cabañas – RD21/0012/0014 Larqué -RD21/0012/0002 Llurba - RD21/0012/0001
Primary care pediatricians. Barcelona Heath Hub, Mediktor, Ordesa, Netslé, Massimo, Philips, General electrics, Siemens	SENeo, AEPap, EAP,	Consensus Guideline for the Integrated Follow Up of Late Preterm Infants	LLurba- RD21/0012/0001 Larqué -RD21/0012/0002 Gómez- RD21/0012/0003 Loureiro -RD21/0012/0006 Mesa - RD21/0012/0008 Pallás - RD21/0012/0009 Rodríguez -RD21/0012/0012 Cabañas - RD21/0012/0014 Boronat - RD21/0012/0015 Cabero - RD21/0012/0016
Primary care pediatricians Barcelona Heath Hub, Mediktor, Ordesa, Netslé, Massimo, Philips, General electrics, Siemens	Webinar, AEP (Asociación Española de Pediatría) AEPap (Asociación Española de Pediatría de Atención Primaria) SENeo (Sociedad Española de Neonatología)	Clinical guidelines for a multidisciplinary hospital follow-up calendar and Primary Care of the newborn with risk of neurodevelopment impairment	Cabañas-RD21/0012/0014 Gómez- RD21/0012/0003, Pallás- RD21/0012/0009 , García- RD21/0012/0017, Boronat - RD21/0012/ 0015, Cabero - RD21/0012/ 0016, Llurba - RD21/0012/ 0001, Loureiro - RD21/0012/ 0006, Couce - RD21/0012/ 0018, Martínez - RD21/0012/ 0026
Midwifes and mothers Banco de Leche Humana	Breasfeeding primary care groups of mothers, Infographics, webinars, videos, social media	Information for mothers on strategies to improve breastfeeding	Boronat -RD21/0012/00015 Cabañas - RD21/0012/0014 Cabero - RD21/0012/0016 Mesa - RD21/0012/0008 Gómez - RD21/0012/0003 García - RD21/0012/0017 Couce - RD21/0012/0021
Midwifes, primary care pediatricians and nurses and mothers Banco de leche humana	Webmail, webinar, video, social media	Protocols for selecting and recruiting donors and human milk collection in Primary Care centers	Boronat -RD21/0012/00015 Cabañas - RD21/0012/0014 Cabero - RD21/0012/0016 Mesa - RD21/0012/0008 Gómez - RD21/0012/0003 García - RD21/0012/0017 Couce - RD21/0012/0021

Primary care pediatricians, AVAPACE (Asociación Valencia de Ayuda a la parálisis cerebral), ATE (Asociación de Pacientes con Atresia de Esofago), EFCNI: Diversas asociaciones de padres de prematuros, enfermedades raras, a nivel nacional y europeo Fundación Save the Children Barcelona Heath Hub, Mediktor, Ordesa, Netslé, Massimo, Philips, General electrics, Siemens	Webmail, webinar, video, social media, AEP (Asociación Española de Pediatría) AEPap (Asociación Española de Pediatría de Atención Primaria) SENeo (Sociedad Española de Neonatología)	Guidelines for the promotion of cardiovascular health in children and adults, as well as the prevention and treatment of obesity and its comorbidities	Larqué RD21/0012/0002 Gómez - RD21/0012/0003 Mesar - RD21/0012/0008 Cabero - RD21/0012/0016
Primary care pediatricians, EFCNI: Diversas asociaciones de padres de prematuros, enfermedades raras, a nivel nacional y europeo Fundación Save the Children Barcelona Heath Hub, Mediktor, Ordesa, Netslé, Massimo, Philips, General electrics, Siemens	webinar, video, social media, AEP (Asociación Española de Pediatría) AEPap (Asociación Española de Pediatría de Atención Primaria) SENeo (Sociedad Española de Neonatología)	Clinical guidelines for prevention, early detection and follow-up of chronic serious diseases children (diabetes, chronic renal failure, celiac disease, prematurity	López-Herce – RD21/0012/0011 Ródriguez- RD21/0012/0025 Rey – RD21/0012/002 Mesa - RD21/0012/0008 Cabañas - RD21/0012/0014 Cabero - RD21/0012/0016 CA9
Schools and parents associations	Inphografics, Webmail, webinar, video, social media,	Recommendations of education activities of health care education in high risk children and families	López-Herce – RD21/0012/0011 Ródriguez- RD21/0012/0025 Rey – RD21/0012/0020 Mesa - RD21/0012/0008 Cabañas - RD21/0012/0014 Cabero - RD21/0012/0016 CA9
Schools and parents associations, Ordesa, Netslé, Massimo.	Webmail, webinar, video, social media, EFCNI: Diversas asociaciones de padres de prematuros, enfermedades raras, a nivel nacional y europeo	Nutritional protocols for celiac patients	Rodríguez - D21/0012/0012 Larqué - RD21/0012/0002 Lópeaz-Herce - RD21/0012/0011 Ródriguez- RD21/0012/0025 Rey – RD21/0012/0020 Couce - RD21/0012/0021
Primary care pediatricians Ordesa, Netslé, Massimo	Webinar, EFCNI: Diversas asociaciones de padres de prematuros, enfermedades raras, a nivel nacional y europeo	Guidelines on food allergy management	Rodríguez - D21/0012/0012 Larqué - RD21/0012/0002 Lópeaz-Herce - RD21/0012/0011 Ródriguez- RD21/0012/0025 Rey – RD21/0012/0020 Couce - RD21/0012/0021

Maternal and Child care-givers.	Webmail, webinar, video, social media, Safe the Children, Asociación Nacional de Infértiles , OMS, European Institute for	Guideline of how to introduce gender- and ethnically sensitive approaches and shared decision-making	All groups
Maternal and Child care-givers.	Webmail, webinar, video, social media, Safe the Children, Asociación Nacional de Infértiles	Best practice guide about shared decision-making perspectives in healthcare	All groups
Maternal and Child care-givers, Safe the Children, Asociación Nacional de Infértiles ,	Webmail, webinar, video, social media, Safe the Children, Asociación Nacional de Infértiles , OMS, European Institute for Gerder Equality	Best practice guide about gender and ethnic equality perspectives in healthcare	All groups
Maternal and Child care-givers	Webmail, webinar, video, social media	Infographics to inform healthcare professionals about parents	All groups

RICORS Code	RICORS Leader:
RD21/0012/0001	Elisa Llurba Olivé

REQUESTED BUDGET

DETAILED BUDGET FOR THE PROPOSED RESEARCH PROGRAMME

GROUP Nº	1	PI SHORT NAME	E Llurba
		COST (€)	JUSTIFICATION
PERSONNEL		114,000	Investigator (40 hours/week)
GOOD AND SERVICES		27,000	Laboratory equipment and statistical analysis of results
TRAVEL		3,000	Meetings and dissemination of results
TOTAL		€ 144,000	

GROUP Nº	2	PI SHORT NAME	N Boronat
		COST (€)	JUSTIFICATION
PERSONNEL		114,000	Investigator (40 hours/week)
GOOD AND SERVICES		27,000	Laboratory equipment and statistical analysis of results
TRAVEL		3,000	Meetings and dissemination of results
TOTAL		€ 144,000	

GROUP Nº	3	PI SHORT NAME	F Cabañas
		COST (€)	JUSTIFICATION
PERSONNEL		114,000	Investigator (40 hours/week)
GOOD AND SERVICES		27,000	Laboratory equipment and statistical analysis of results
TRAVEL		3,000	Meetings and dissemination of results
TOTAL		€ 144,000	

GROUP Nº	4	PI SHORT NAME	C Pallás
		COST (€)	JUSTIFICATION
PERSONNEL		114,000	Investigator (40 hours/week)
GOOD AND SERVICES		27,000	Laboratory equipment and statistical analysis of results
TRAVEL		3,000	Meetings and dissemination of results
TOTAL		€ 144,000	

GROUP Nº	5	PI SHORT NAME	MD Gómez-Roig
		COST (€)	JUSTIFICATION
PERSONNEL		114,000	Investigator (40 hours/week)
GOOD AND SERVICES		27,000	Laboratory equipment and statistical analysis of results
TRAVEL		3,000	Meetings and dissemination of results
TOTAL		€ 144,000	

GROUP Nº	6	PI SHORT NAME	O García-Algar
		COST (€)	JUSTIFICATION
PERSONNEL		114,000	Investigator (40 hours/week)
GOOD AND SERVICES		27,000	Laboratory equipment and statistical analysis of results
TRAVEL		3,000	Meetings and dissemination of results
TOTAL		€ 144,000	

GROUP Nº	7	PI SHORT NAME	J López-Herce
		COST (€)	JUSTIFICATION
PERSONNEL		114,000	Investigator (40 hours/week)
GOOD AND SERVICES		27,000	Laboratory equipment and statistical analysis of results
TRAVEL		3,000	Meetings and dissemination of results
TOTAL		€ 144,000	

GROUP Nº	8	PI SHORT NAME	G Martínez
		COST (€)	JUSTIFICATION
PERSONNEL		114,000	Investigator (40 hours/week)
GOOD AND SERVICES		27,000	Laboratory equipment and statistical analysis of results
TRAVEL		3,000	Meetings and dissemination of results
TOTAL		€ 144,000	

GROUP Nº	9	PI SHORT NAME	E Larqué
GROUP Nº		PI SHORT NAME	
GROUP Nº		PI SHORT NAME	
GROUP Nº		PI SHORT NAME	
GROUP Nº		PI SHORT NAME	

GROUP Nº	9	PI SHORT NAME	E Larqué
		COST (€)	JUSTIFICATION
PERSONNEL		114,000	Investigator (40 hours/week)
GOOD AND SERVICES		27,000	Laboratory equipment and statistical analysis of results
TRAVEL		3,000	Meetings and dissemination of results
TOTAL		€ 144,000	

GROUP Nº	10	PI SHORT NAME	B Loureiro
		COST (€)	JUSTIFICATION
PERSONNEL		57,000	Investigator (20 hours/week)
GOOD AND SERVICES		13,500	Laboratory equipment and statistical analysis of results
TRAVEL		1,500	Meetings and dissemination of results
TOTAL		€ 72,000	

GROUP Nº	11	PI SHORT NAME	MD Mesa
		COST (€)	JUSTIFICATION
PERSONNEL		114,000	Investigator (40 hours/week)
GOOD AND SERVICES		27,000	Laboratory equipment and statistical analysis of results
TRAVEL		3,000	Meetings and dissemination of results
TOTAL		€ 144,000	

GROUP Nº	12	PI SHORT NAME	A. Rodríguez-Nuñez
		COST (€)	JUSTIFICATION
PERSONNEL		57,000	Investigator (20 hours/week)
GOOD AND SERVICES		13,500	Laboratory equipment and statistical analysis of results
TRAVEL		1,500	Meetings and dissemination of results
TOTAL		€ 72,000	

GROUP Nº	13	PI SHORT NAME	C Galán
GROUP Nº		PI SHORT NAME	
GROUP Nº		PI SHORT NAME	
GROUP Nº	13	PI SHORT NAME	C Galán
		COST (€)	JUSTIFICATION

GROUP Nº		PI SHORT NAME	
PERSONNEL	57,000		Investigator (20 hours/week)
GOOD AND SERVICES	13,500		Laboratory equipment and statistical analysis of results
TRAVEL	1,500		Meetings and dissemination of results
TOTAL	€ 72,000		

GROUP Nº		PI SHORT NAME	
GROUP Nº	14	PI SHORT NAME	M Jesús Cabero
	COST (€)		JUSTIFICATION
PERSONNEL	57,000		Investigator (20 hours/week)
GOOD AND SERVICES	13,500		Laboratory equipment and statistical analysis of results
TRAVEL	1,500		Meetings and dissemination of results
TOTAL	€ 72,000		

GROUP Nº	15	PI SHORT NAME	D Marre
	COST (€)		JUSTIFICATION
PERSONNEL	114,000		Investigator (40 hours/week) and investigator (7 hours/week)
GOOD AND SERVICES	27,000		Laboratory equipment and statistical analysis of results
TRAVEL	3,000		Meetings and dissemination of results
TOTAL	€ 144,000		

GROUP Nº	16	PI SHORT NAME	Mª Luz Couce
	COST (€)		JUSTIFICATION
PERSONNEL	57,000		Investigator (20 hours/week)
GOOD AND SERVICES	13,500		Laboratory equipment and statistical analysis of results
TRAVEL	1,500		Meetings and dissemination of results
TOTAL	€ 72,000		

GROUP Nº	17	PI SHORT NAME	P Fernández de la Llama
	COST (€)		JUSTIFICATION
PERSONNEL	114,000		Investigator (40 hours/week)
GOOD AND SERVICES	27,000		Laboratory equipment and statistical analysis of results
TRAVEL	3,000		Meetings and dissemination of results

GROUP Nº		PI SHORT NAME	
TOTAL		€ 144,000	

GROUP Nº	18	PI SHORT NAME	I Herraiz
GROUP Nº		PI SHORT NAME	
GROUP Nº		PI SHORT NAME	
GROUP Nº		PI SHORT NAME	
		COST (€)	JUSTIFICATION
PERSONNEL		57,000	Investigator (20 hours/week)
GOOD AND SERVICES		13,500	Laboratory equipment and statistical analysis of results
TRAVEL		3,000	Meetings and dissemination of results
TOTAL		€ 73,500	

GROUP Nº	19	PI SHORT NAME	L Martínez
		COST (€)	JUSTIFICATION
PERSONNEL		57,000	Investigator (20 hours/week)
GOOD AND SERVICES		13,500	Laboratory equipment and statistical analysis of results
TRAVEL		1,500	Meetings and dissemination of results
TOTAL		€ 72,000	

GROUP Nº	20	PI SHORT NAME	J Antonio Martínez
		COST (€)	JUSTIFICATION
PERSONNEL		57,000	Investigator (20 hours/week)
GOOD AND SERVICES		13,500	Laboratory equipment and statistical analysis of results
TRAVEL		1,500	Meetings and dissemination of results
TOTAL		€ 72,000	

RICORS Code	RICORS Leader:
RD21/0012/0001	Elisa Llurba Olivé

REQUESTED BUDGET

BUDGET JUSTIFICATION

Describe the consistency between resources, capabilities and objectives. Max. 2 pages (10,700 characters)

RICORS Maternal and Children Consortium is an ambitious program that will cover relevant aspects of Maternal and Child Health as proposed by the RICORS Maternal and Children Consortium in its constitution.

1. Personal justification.
The most relevant component of the budget is the contract of full or partial time investigators.
The total amounts 38.000,00 euros x 3 years x 12 groups with full time contracts (1.368.000,00 euros) and 19.000,00 euros x 3 years x 8 groups with partial time contract (456.000,00 euros)
The groups involved in this new RICORS have important and time consuming tasks to face. However, a substantial number of these groups are constituted by clinical researchers who have to fulfill their daily clinical activities in first place and thereafter actively participate in the tasks required by the network. In our country, there is **no protected time** for clinical researchers, and their tasks have to be performed after the usual working hours.This implies that clinical researchers have only very limited time to perform some of the tasks required by the different studies.
Therefore, clinical researchers will undertake the task of designing the studies to be performed, the protocols, the electronic data sheet registry, recruit the patients and perform sampling of biological material under the leadership of the Group Leader. However, there is a need for an additional researcher devoted to the project.

The contracted personal will:
a. Organize meetings beetween researchers of the hospitals and the clinical associated groups of the primary care in which the PI will inform on the ongoing of the research.
b. Train the study personnel of primary care involved in the projects
c. Keep continuous contact with the rest of the Groups of new RICORS
d. Collect, process, and store samples in the Biobank
e. Ship samples to the central laboratories when requested
f. Retrieve clinical and analytical data from the recruited patients and upload them in the general data base
g. In those groups that develop new laboratory or clinical methodologies the researcher will contribute to the development of these aspects of the tasks assigned to his/her group.
h. Prepare abstracts for dissemination of results
i. Contribute to the writing of manuscripts and guidelines of the WPs
j. Keep pace of the adequate ongoing of the group tasks.
k. Contribute to the validation of the apps generated by the diferent WPs in the programm.
l. Collect data about families and healthcare professionals' perspectives on gender- and ethnically sensitive approaches.
m. Organize meetings beetween researchers and families implicated in the programm.

1.1 Full time Scientific Assistant to the Coordinator of RICORS Maternal and Children Consortium

The enormous complexity of coordinating 20 research groups (RG) with a total of approximately 170 researchers and 26 clinical associated groups (CA) with a total of approximately 150 clinical investigators involved in complex clinical studies requires a substantial support. The post-doctoral contract will be used for a scientific assisstant, that will be an expert in laboratory and analytical methodology including statistical analysis. The scientific assistant will run the databases of the different Workpackages and supervise the correct data input, validate data, perform statistical analysis and establish priorities

The Network Manager is responsable for information, budget, web page, and organizing meetings, conference calls. The budget corresponding to Coordination should be assigned to Hospital de la Santa Creu i Sant Pau (RD21/0012/0001)
The Scientific Assistant in close cooperation with the Network Coordinator (Dra. Elisa Llurba) will undertake the tasks of keeping pace of the ongoing activity of the 20 research groups by periodic direct electronic contact, supervision of the data base inputs, analytical and sampling advising, providing groups with relevat inforamation and helping with study design, statistics, writing of abstracts and manuscripts and dissemination of achievements.

2. Good and Services.

The costs of the biobank generated for processing and the storage of the samples derived from the diferents studies of the new programm are reflected in Good and Services. Also, the groups will have to ship biological samples in dry ice to the central laboratories periodically and the cost of shipment is also reflected in Good and Services.

Some research groups have to make specific determinations in blood and tissue samples (ELISAs, DNA or RNA extraction,) and these determinations are reflected in this budget.
The data analysis of the results obtained is reflected in Good and Services.
All groups have and individual amount for publications in its budget because the last year of the RICORS the results of the projects will be published. Moreover, at present the most relevant peer reviewed journals require the payment of fees for accepted papers to be published. The average cost is around 1000-1200 USD.
Organitzation of webinars and meetings between researchers of the programm (hospitals and primary car) or with families will be paid in this budget.

3. Travel Justification
The groups that integrate the new RICORS need to gather periodically to inform on the results of their respective tasks.
In this regard at least twice a year we will hold a Scientific Meeting with oral communications and discussion of the circumstances implied in the tasks of all the groups and perform troubleshooting, and prepare scientific communications for dissemination in the form of abstracts or manuscripts of the achievements of the new RICORS.
The groups need to travel to international meetings to present their results.
The Coordinator of the study will need to frequently visit study groups and represent the network at national and International scientific meetings.

RICORS Code	RICORS Leader:
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ANNEXES (Text)

Max. 2 pages (10,700 characters)

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ANNEXES (Images)

Max. 1 figure (jpg format)

RICORS Call: Statement of the Programme RICORS Coodinator

Aim: describe the proposal Research Activity Programme: objectives, work plan, work packages, deliverables and milestones.

⚠ The structure of this template has been designed to ensure that the important aspects of your proposal are presented in a way that will enable experts to make an effective assessment against the evaluation criteria.

⚠ The font type and size recommended is Arial 9 points. Please respect the page limits and do not take it as a target either! It is in your interest to keep your text as concise as possible, since experts rarely view unnecessarily long documents in a positive light.

RICORS. Organizational structure

RICORS Coordinator: scientific management ot the network (RICORS), development of training programmes, and head of the dissemination and visibility of the network (RICORS).

Progamme Leader: coordination of the Research Programmes, and monitoring compliance with their objectives.

Research group: set of researchers grouped around a Principal Investigator (PI) who collaborates in the study of the thematic field of application. They should act in coordination in the development and implementation of scientific programs within the network (RICORS).

Clinical research group: set of researches directly related to the patient care activities.

Known Issues

Section 1. List of PI participants.

Research: main focus of the research activity developed by the group, values: Basic; Epidemiologycal; Clinical

Group: characterization of the research group, values: Research; Clinical

Section 11. List of Deliverables

Dissemination level: Use one of the following values: Public (publication, fully open, web); Confidential (restricted under conditions)

Section 12. List of Milestones

Means of verification: show how you will confirm that the milestone has been attained.