

# EPIPAGE 2 - Epidemiological study on low gestational age infants 2

Responsable(s) :Ancel Pierre-Yves, U953 - Unité de recherche épidémiologique en santé périnatale et santé des femmes et des enfants

Date de modification : 21/01/2014 | Version : 2 | ID : 3411

## Général

### Identification

Nom détaillé Epidemiological study on low gestational age infants 2

Sigle ou acronyme EPIPAGE 2

Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.) CNIL n°911009 / CCTIRS n°10.626 / CPP SC-2873

### Thématiques générales

Domaine médical Gynecology/ obstetrics  
Pediatrics

Déterminants de santé Genetic

Mots-clés Perinatality, neonatal mortality and morbidity (respiratory, neurological, infectious, metabolic), neural development (motor, sensory, cognitive), growth), handicaps

### Responsable(s) scientifique(s)

Nom du responsable Ancel

Prénom Pierre-Yves

Adresse HOPITAL ST VINCENT DE PAUL- 82 AVENUE  
DENFERT ROCHEREAU- BATIMENT LELONG-75014  
PARIS

Téléphone +33 (0)1 56 01 83 63

Email pierre-yves.ancel@inserm.fr

Laboratoire U953 - Unité de recherche épidémiologique en santé périnatale et santé des femmes et des enfants

Organisme INSERM

## Collaborations

|                                                           |     |
|-----------------------------------------------------------|-----|
| Participation à des projets, des réseaux, des consortiums | Yes |
|-----------------------------------------------------------|-----|

## Financements

|              |       |
|--------------|-------|
| Financements | Mixed |
|--------------|-------|

|            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Précisions | Ce projet a été financé grâce au soutien de:1) l'Institut de Recherche en Santé Publique / Institut Thématique Santé Publique, et des partenaires financeurs suivants : Ministère de la santé et des sports, Ministère délégué à la recherche, Institut National de la Santé et de la Recherche Médicale, Institut National du Cancer et Caisse Nationale de solidarité pour l'Autonomie.2) la fondation PREMUP3) Programme EQUIPEX des Investissements d'avenir dans le cadre de la plateforme RE-CO-NAI |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## Gouvernance de la base de données

|                                             |                                                                    |
|---------------------------------------------|--------------------------------------------------------------------|
| Organisation(s) responsable(s) ou promoteur | Institut National de la Santé et de la Recherche Médicale - INSERM |
|---------------------------------------------|--------------------------------------------------------------------|

|                          |                |
|--------------------------|----------------|
| Statut de l'organisation | Secteur Public |
|--------------------------|----------------|

## Contact(s) supplémentaire(s)

## Caractéristiques

### Type de base de données

|                         |                 |
|-------------------------|-----------------|
| Type de base de données | Study databases |
|-------------------------|-----------------|

|                                               |              |
|-----------------------------------------------|--------------|
| Base de données issues d'enquêtes, précisions | Cohort study |
|-----------------------------------------------|--------------|

|                                         |                                                 |
|-----------------------------------------|-------------------------------------------------|
| Origine du recrutement des participants | A selection of health institutions and services |
|-----------------------------------------|-------------------------------------------------|

|                                                                                               |    |
|-----------------------------------------------------------------------------------------------|----|
| Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle | No |
|-----------------------------------------------------------------------------------------------|----|

|                                                                          |                                            |
|--------------------------------------------------------------------------|--------------------------------------------|
| Informations complémentaires concernant la constitution de l'échantillon | Prospective. End of inclusions: 01/12/2011 |
|--------------------------------------------------------------------------|--------------------------------------------|

### Objectif principal

More than 10 years are passed since the beginning of the EPIPAGE study. The evolutions occurred since justify the creation of a new cohort.

The main objectives of EPIPAGE 2 are:

- 1) Study the becoming of extremely premature children and their families
- 2) The evaluation of care organization effects and medical practice on premature children's health and development
- 3) Research of causes and consequences of prematurity
- 4) Study the path of the different families and the decisions process at the moment of birth and intensive care
- 5) The needs analysis of medical and educational care

One of the originalities of the study is to have permitted the creation of complementary and multidisciplinary projects, in order to reply and deepen to question difficult to handle on the children of the cohort. These projects, based on the same structure of EPIPAGE 2, needs additional investigations and an own funding.

A total of 8 studies have been developed in the field of brain imaging, bio-markers, nutrition, mother-child interaction and ethics:

- ETHIQUE (decision process leading to survival or death of children born between 22 and 26 weeks of amenorrhea)
- EPIFLORE (study of the introduction of the intestinal microbiota)
- EPIRMEX (Study of the executive functions and of the language development, depending on anomalies detected through NRM)
- BIOPAG (Identification of the early bio-markers of pathologies from an umbilical cord sample (DNA, RNA))
- OLIMPE (Study of the existing links between the quality of early mother-child interactions and the neural and developmental becoming)
- CHORHIST (Research of chorioamniontides through anatomo-pathological analysis of placenta)
- EPINUTRI (Study of the associations of the intake of polyunsaturated fatty acids, iron intake and neurological becoming of extremely premature children)
- EPIPAIN 2 (treatment of painful movements in

neonatal intensive care.

#### RE-CO-NAI platform

EPIPAGE 2 is one of the two cohorts constituting the RE-CO-NAI platform, together with the ELFE cohort.

The general objective of this platform is to create an infrastructure offering the measures required for collecting, highly secured storage and distribution of data concerning the pregnancy, the birth and the child.

The research platform consist of cohorts of infants followed since birth will allow to study, in a global and multidisciplinary way, the stakes on health, development and socialization of children.

It will in addition provide substantial visibility in the world of academic research (French and international), but also with regards to bodies, associations, and industries that have interests in children. As such, it will allow for an optimized valorization of the data collected and will facilitate the dissemination of data.

#### Critères d'inclusion

EPIPAGE 2 is a population based perspective cohort. All the children born in 25 regions of France, extremely premature (22-26 weeks of amenorrhea) on 8 months, highly premature (27-31 weeks of amenorrhea) on 6 months and moderately premature (32-34 weeks of amenorrhea) on 1 month. A control group of full-born children will be constituted from Elfe study. Children of families having expressed a refusal will not be included. In this case, the information from the health certificate of the 8th day could be used to characterize the population concerned.

#### Type de population

##### Age

Newborns (birth to 28 days)  
Infant (28 days to 2 years)  
Early childhood (2 to 5 years)  
Childhood (6 to 13 years)

##### Population concernée

General population

##### Sexe

Male  
Woman

##### Champ géographique

National

##### Détail du champ géographique

21 regions of metropolitan France and 4 overseas regions (Martinique, Guadeloupe, Guyana, Réunion)

| Collecte                                             |                                                                                                                                                                                                                                                             |
|------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Dates                                                |                                                                                                                                                                                                                                                             |
| Année du premier recueil                             | 04/2011                                                                                                                                                                                                                                                     |
| Taille de la base de données                         |                                                                                                                                                                                                                                                             |
| Taille de la base de données (en nombre d'individus) | [1000-10 000[ individuals                                                                                                                                                                                                                                   |
| Détail du nombre d'individus                         | - 8398 prématurés/premature births and Induced therapeutic abortions/avortements - 7595 enfants/children                                                                                                                                                    |
| Données                                              |                                                                                                                                                                                                                                                             |
| Activité de la base                                  | Current data collection                                                                                                                                                                                                                                     |
| Type de données recueillies                          | Clinical data<br>Declarative data<br>Biological data                                                                                                                                                                                                        |
| Données cliniques, précisions                        | Direct physical measures<br>Medical registration                                                                                                                                                                                                            |
| Détail des données cliniques recueillies             | Clinical examination at inclusion and during the follow-up (birth, 2 years, 5years, 8 years, 11-12 years). Information collected through the clinical examination: motor, sensory, cognitive development, height and weight growth, respiratory pathologies |
| Données déclaratives, précisions                     | Paper self-questionnaire<br>Face to face interview                                                                                                                                                                                                          |
| Détail des données déclaratives recueillies          | Clinical examination at inclusion and during the follow-up (birth, 2 years, 5years, 8 years, 11-12 years). Information collected through the clinical examination: motor, sensory, cognitive development, height and weight growth, respiratory pathologies |
| Données biologiques, précisions                      | Biological data from coming from the medical record. For a sub-sample of children (n=150), umbilical cord blood has been taken                                                                                                                              |
| Existence d'une biothèque                            | Yes                                                                                                                                                                                                                                                         |
| Contenu de la biothèque                              | Whole blood<br>Cord blood<br>Fluids (saliva, urine, amniotic fluid, ?)<br>Tissues                                                                                                                                                                           |

## Others

| Détail des éléments conservés                 | Maternal blood, umbilical cord blood, stools of the newborn. The constitution of the biological collections that will allow a number of early exposures, as well as markers of health condition, is one of the specific objectives of the two studies of the RE-CO-NAI platform.                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Paramètres de santé étudiés                   | Health event/morbidity<br>Health event/mortality<br>Quality of life/health perception                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Modalités                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Mode de recueil des données                   | At birth (inclusion), clinical data are collected from the medical record and the medical teams, as well as information from the mother about pregnancy, delivery, intensive care (self-questionnaire and interview with the mother). During the follow-up, data are collected at 2, 5, 8 and 12 years. -A clinical and psychological check-up will be realized at 5, 8 and 12 years (motor, sensory, cognitive development, height and weight growth, respiratory pathologies) - Data concerning child's health, his development, his schooling, his quality of life, possible handicaps, consequences on the family are collected through a self-questionnaire submitted to the mother at 1, 2, 5, 8 and 12 years. |
| Procédures qualité utilisées                  | Coherence request during and after computer data entry. Missing data checked back to the original file. Subjects and doctors reminders for follow-up visits. Internal quality audit report. Patients receive information about the use of their data.                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Suivi des participants                        | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Détail du suivi                               | Children will be followed until 12 years old.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Appariement avec des sources administratives  | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Sources administratives appariées, précisions | SNIIRAM (file under preparation)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Valorisation et accès                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Valorisation et accès                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Lien vers le document                         | <a href="http://www.hal.inserm.fr/EPIPAGE">http://www.hal.inserm.fr/EPIPAGE</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Description                                   | List of publications in HAL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

|                       |                                                                                                                                                                                     |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Lien vers le document | <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=epipage+OR+25541510[uid]+OR+19932945[uid]">http://www.ncbi.nlm.nih.gov/pubmed/?term=epipage+OR+25541510[uid]+OR+19932945[uid]</a> |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|             |                                |
|-------------|--------------------------------|
| Description | List of publications in Pubmed |
|-------------|--------------------------------|

## Accès

|                                                                                                                  |                                                                                                                                                     |
|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition) | Data utilization possible for academic teams. Access to every interested research team after an evaluation of the project by the scientific council |
|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|

|                            |                                 |
|----------------------------|---------------------------------|
| Accès aux données agrégées | Access on specific project only |
|----------------------------|---------------------------------|

|                                 |                                 |
|---------------------------------|---------------------------------|
| Accès aux données individuelles | Access on specific project only |
|---------------------------------|---------------------------------|