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

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## General

### Identification

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| Detailed name | Epidemiological study on low gestational age infants 2 |
| Sign or acronym | EPIPAGE 2 |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL n°911009 / CCTIRS n°10.626 / CPP SC-2873 |

### General Aspects

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| Medical area | Gynecology/ obstetrics<br>Pediatrics |
| Health determinants | Genetic |
| Keywords | Perinatality, neonatal mortality and morbidity (respiratory, neurological, infectious, metabolic), neural development (motor, sensory, cognitive), growth), handicaps |

### Scientific investigator(s) (Contact)



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| | enfants |
| Organization | INSERM |

## Collaborations

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| Participation in projects, networks and consortia | Yes |

## Funding

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| Funding status | Mixed |
| Details | 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 |

## Governance of the database

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| Sponsor(s) or organisation(s) responsible | Institut National de la Santé et de la Recherche Médicale - INSERM |
| Organisation status | Public |

## Additional contact

# Main features

## Type of database

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| Type of database | Study databases |
| Study databases (details) | Cohort study |
| Database recruitment is carried out by an intermediary | A selection of health institutions and services |
| Database recruitment is carried out as part of an interventional study | No |
| Additional information regarding sample selection. | Prospective. End of inclusions: 01/12/2011 |

## Database objective

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| Main objective | More than 10 years are passed since the beginning of the EPIPAGE study. The evolutions occurred since justify the creation of a new cohort.<br><br>The main objectives of EPIPAGE 2 are:<br><br>1) Study the becoming of extremely premature children and their families<br>2) The evaluation of care organization effects and medical practice on premature children's health and development<br>3) Research of causes and consequences of prematurity<br>4) Study the path of the different families and the decisions process at the moment of birth and intensive care<br>5) The needs analysis of medical and educational care<br><br>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.<br>A total of 8 studies have been developed in the field of brain imaging, bio-markers, nutrition, mother-child interaction and ethics:<br><br>- ETHIQUE (decision process leading to survival or death of children born between 22 and 26 weeks of amenorrhea)<br>- EPIFLORE (study of the introduction of the intestinal microbiota)<br>- EPIRMEX (Study of the executive functions and of the language development, depending on anomalies detected through NRM)<br>- BIOPAG (Identification of the early bio-markers of pathologies from an umbilical cord sample (DNA, RNA)<br>- OLIMPE (Study of the existing links between the quality of early mother-child interactions and the neural and developmental becoming)<br>- CHORHIST (Research of chorioamniontides through anatomo-pathological analysis of placenta)<br>- EPINUTRI (Study of the associations of the intake of polyunsaturated fatty acids, iron intake and neurological becoming of extremely premature children)<br>- EPIPAIN 2 (treatment of painful movements in |

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| | neonatal intensive care.<br><br>RE-CO-NAI platform<br>EPIPAGE 2 is one of the two cohorts constituting the RE-CO-NAI platform, together with the ELFE cohort.<br>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.<br>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.<br>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. |
| Inclusion criteria | 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. |
| **Population type** | |
| Age | Newborns (birth to 28 days)<br>Infant (28 days to 2 years)<br>Early childhood (2 to 5 years)<br>Childhood (6 to 13 years) |
| Population covered | General population |
| Gender | Male<br>Woman |
| Geography area | National |
| Detail of the geography area | 21 regions of metropolitan France and 4 overseas regions (Martinique, Guadeloupe, Guyana, Réunion) |

## Data collection

### Dates

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| Date of first collection (YYYY or MM/YYYY) | 04/2011 |

### Size of the database

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| Size of the database (number of individuals) | [1000-10 000[ individuals |
| Details of the number of individuals | - 8398 prématurés/premature births and Induced therapeutic abortions/avortements - 7595 enfants/children |

### Data

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| Database activity | Current data collection |
| Type of data collected | Clinical data<br>Declarative data<br>Biological data |
| Clinical data (detail) | Direct physical measures<br>Medical registration |
| Details of collected clinical data | 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 |
| Declarative data (detail) | Paper self-questionnaire<br>Face to face interview |
| Details of collected declarative data | 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 |
| Biological data (detail) | Biological data from coming from the medical record. For a sub-sample of children (n=150), umbilical cord blood has been taken |
| Presence of a biobank | Yes |
| Contents of biobank | Whole blood<br>Cord blood<br>Fluids (saliva, urine, amniotic fluid, ?) |

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| | Tissues<br>Others |
| Details of biobank content | 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. |
| Health parameters studied | Health event/morbidity<br>Health event/mortality<br>Quality of life/health perception |

## Procedures

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| Data collection method | 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. |
| Quality procedure(s) used | Coherence request during and after computer data entry. Missing data checked back to the original file. Subjects an doctors remainders for follow-up visits. Internal quality audit report. Patients receive information about the use of their data. |
| Participant monitoring | Yes |
| Details on monitoring of participants | Children will be followed until 12 years old. |
| Links to administrative sources | Yes |
| Linked administrative sources (detail) | SNIIRAM (file under preparation) |

# Promotion and access

## Promotion

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| Link to the document | http://www.hal.inserm.fr/EPIPAGE |

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| Description | List of publications in HAL |
| Link to the document | http://www.ncbi.nlm.nih.gov/pubmed/?term=epipage+OR+25541510[uid]+OR+19932945[uid] |
| Description | List of publications in Pubmed |

| Access | |
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| Terms of data access (charter for data provision, format of data, availability delay) | Data utilization possible for academic teams. Access to every interested research team after an evaluation of the project by the scientific council |
| Access to aggregated data | Access on specific project only |
| Access to individual data | Access on specific project only |