# EREMI - Longitudinal study in patients aged 0 to 15 years hospitalised for at least 3 days after receiving at least one drug: risk of adverse drug reactions associated with off-label/unlicensed prescriptions

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Last update : 09/06/2020 | Version : 1 | ID : 39007

## General

### Identification

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| Detailed name | Longitudinal study in patients aged 0 to 15 years hospitalised for at least 3 days after receiving at least one drug: risk of adverse drug reactions associated with off-label/unlicensed prescriptions |
| Sign or acronym | EREMI |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | MMS/MTE/AR1411279 |

### General Aspects

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| Medical area | Pediatrics |
| Pathology (details) | Adverse drug reactions |
| Health determinants | Iatrogenic<br>Medicine |
| Keywords | drug, ADEs, Adverse drug episodes, adverse effect, market authorisation, prescription, Hospitalisation, MA, child, adolescent |

### Scientific investigator(s) (Contact)

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| Organization | Hospices Civils de Lyon (HCL) |

## Collaborations

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| Participation in projects, networks and consortia | Yes |
| Details | CIC Pédiatrique - Hôpital Femme-Mère-Enfant, Hospices Civils de Lyon (HCL) / CIC pédiatrique - Hôpital Robert Debré, Assistance publique ? Hôpitaux de Paris (AP-HP) |

## Funding

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| Funding status | Public |
| Details | ANSM Financing 2012 - Axis 2: Analysis of off-label drug use |

## Governance of the database

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| Sponsor(s) or organisation(s) responsible | Hôpital Femme-Mère-Enfant, Hospices Civils de Lyon (HCL) |
| Organisation status | Public |
| Sponsor(s) or organisation(s) responsible | Hôpital Robert Debré, Assistance publique ? Hôpitaux de Paris (AP-HP) |
| Organisation status | Public |
| Presence of scientific or steering committees | Yes |

## Additional contact

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## 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<br>A population file |
| Database recruitment is is made on the basis of: | Medication(s) taken |
| Database recruitment is carried out as part of an interventional study | No |
| Additional information regarding sample selection. | Automated prospective extraction of drug administrations from the HCL Hospital Information System / Active and spontaneous detection of adverse drug events |

### Database objective

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| Main objective | To compare the probability of occurrence of an adverse drug reaction (ADR) after a licensed |

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| | prescription drug versus the probability of occurrence of an ADR after prescribing a drug off-label or unlicensed in patients aged 0-15 years hospitalized at least 3 days<br><br>Secondary objectives:<br>? Compare the proportion of pediatrics inpatients presenting at least one ADR among inpatients with at least one off-labels or unlicensed prescription drug with the proportion of inpatients presenting at least one ADR among inpatients with all licensed prescription drugs<br>? To describe, in terms of marketing autorisation and indications, the medicinal products prescribed by paediatric age group.<br>? Identify the factors influencing the risk of developing ADRs after prescribing a drug<br>? To estimate the seriousness and avoidability of ADRs |
| Inclusion criteria | Children from 0 to 15 years old [0 ; 15[ (including term and preterm newborn infants).<br>Hospitalised for at least 3 days.<br>Receiving at least one medication |
| **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)<br>Adolescence (13 to 18 years) |
| Population covered | Sick population |
| Pathology | Y40-Y59 - Drugs, medicaments and biological substances causing adverse effects in therapeutic use |
| Gender | Male<br>Woman |
| Geography area | Local |
| Detail of the geography area | Hôpital Femme-Mère-Enfant, Hospices Civils de Lyon (HCL) / Hôpital Robert Debré, Assistance publique ? Hôpitaux de Paris (AP-HP) |
| **Data collection** | |
| **Dates** | |
| Date of first collection (YYYY or | 2013 |

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| MM/YYYY) | |
| Date of last collection (YYYY or MM/YYYY) | 2016 |
| **Size of the database** | |
| Size of the database (number of individuals) | [1000-10 000[ individuals |
| Details of the number of individuals | 6227 |
| **Data** | |
| Database activity | Current data collection |
| Type of data collected | Clinical data<br>Declarative data<br>Paraclinical data<br>Biological data<br>Administrative data |
| Clinical data (detail) | Direct physical measures<br>Medical registration |
| Details of collected clinical data | Nature and clinical context of ADEs |
| Declarative data (detail) | Face to face interview<br>Phone interview |
| Details of collected declarative data | Spontaneous reporting of ADEs by medical teams / Aid to reporting ADEs actively detected by the EREMI team |
| Biological data (detail) | Creatinine level |
| Administrative data (detail) | Admission dates, Duration of stay. Extractions from the hospital information system (prescriptions, doses, anthropomorphic and biological data) |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity<br>Health event/mortality<br>Health care consumption and services |
| Care consumption (detail) | Hospitalization<br>Medicines consumption |
| **Procedures** | |

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| Data collection method | During hospitalisation |
| Quality procedure(s) used | Methodology: HCL Paediatric Clinical Investigation Centre; Biostatistics: Biostatistics department of HCL/UMR CNRS 5558; Management of the database: ClinInfo, Lyon |
| Participant monitoring | Yes |
| Monitoring procedures | Monitoring by contact with the participant (mail, e-mail, telephone etc.)<br>Monitoring by contact with the referring doctor<br>Monitoring by crossing with a medical-administrative database |
| Details on monitoring of participants | Duration of monitoring of patients who have had an ADE after discharge: 1 month |
| Links to administrative sources | Yes |
| Linked administrative sources (detail) | PMSI |

## Promotion and access

### Promotion

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| Link to the document | http://adc.bmj.com/content/99/Suppl_2/A62.2.abstract?sid=0943db08-e27a-4da7-bb7a-909ec1a19723; http://www.sciencedirect.com/science/article/pii/S0929693X14719591; http://www.sciencedirect.com/science/article/pii/S0929693X1472130X; http://www.sciencedirect.com/science/article/pii/S0929693X14721311; http://www.sciencedirect.com/science/article/pii/S0929693X14722432 |
| Other information | NCT02852590, protocol available on clinicaltrial.gov (https://clinicaltrials.gov/ct2/show/NCT02852590?term=EREMI&rank=1) |

### Access

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| Presence of document that lists variables and coding procedures | Yes |
| Terms of data access (charter for data provision, format of data, availability delay) | Request from M Behrouz.Kassai (behrouz.kassai-koupai@chu-lyon.fr or Mrs Kim An Nguyen: kim-an.nguyen@chu-lyon.fr |
| Access to aggregated data | Access on specific project only |

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| Access to individual data | Access on specific project only |