

# 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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## General

### Identification

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

Medical area Pediatrics

Pathology (details) Adverse drug reactions

Health determinants Iatrogenic  
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

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

Funding status Public

Details ANSM Financing 2012 - Axis 2: Analysis of off-label drug use

## Governance of the database

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

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  
A population file

Database recruitment 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

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

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

Secondary objectives:

? 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

? To describe, in terms of marketing autorisation and indications, the medicinal products prescribed by paediatric age group.

? Identify the factors influencing the risk of developing ADRs after prescribing a drug

? 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). Hospitalised for at least 3 days. Receiving at least one medication
<b>Population type</b>	
Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) 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 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)
<b>Data collection</b>	
<b>Dates</b>	
Date of first collection (YYYY or	2013

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  
Declarative data  
Paraclinical data  
Biological data  
Administrative data

Clinical data (detail) Direct physical measures  
Medical registration

Details of collected clinical data Nature and clinical context of ADEs

Declarative data (detail) Face to face interview  
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  
Health event/mortality  
Health care consumption and services

Care consumption (detail) Hospitalization  
Medicines consumption

## Procedures

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.) Monitoring by contact with the referring doctor 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

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

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

Access to individual data

Access on specific project only