

# CEMARA - Inflammatory Diseases in Paediatric Rheumatology

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## General

### Identification

Detailed name Inflammatory Diseases in Paediatric Rheumatology

Sign or acronym CEMARA

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL 1187326 (23/05/2007)

### General Aspects

Medical area Rheumatology

Health determinants Genetic

Keywords adverse events, life-threatening, sequelae, embryonic/foetal impairment, neoplasia, Health episodes, death, hospitalisation

### Scientific investigator(s) (Contact)

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Organization UIH) ET INSERM U768 HOPITAL NECKER-ENFANTS MALADES

### Collaborations

Participation in projects, networks and consortia Yes

### Funding

Funding status	Public
Details	CENTRE DE REFERENCE MALADIES RARES « ARTHRITES JUVENILES »
<b>Governance of the database</b>	
Sponsor(s) or organisation(s) responsible	INSERM - Institut National de Santé et Recherche Médicale
Organisation status	Public
Sponsor(s) or organisation(s) responsible	APHP
Organisation status	Public
<b>Additional contact</b>	
<b>Main features</b>	
<b>Type of database</b>	
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.	Inclusion method: Prospective Inclusion cut-off date not determined
<b>Database objective</b>	
Main objective	General objective: To evaluate the risk of the occurrence of serious adverse events under or after exposure to prescribed biotherapy for rheumatoid arthritis. The selected population consists of a growing proportion of patients exposed to early introductory biotherapy from childhood (TNF-Alpha antagonists, IL-1, IL-6, anti-CD20, CTLA-4Ig etc.), sometimes in combination with immunosuppressants Secondary objectives: 1/ To simultaneously assess the risk of the occurrence of serious adverse events (SAE) in the absence of biotherapy for the entire paediatric rheumatology cohort. 2/ To assess the risk of SAEs in the

presence or absence of biotherapy for main sub-cohorts: juvenile idiopathic arthritis, paediatric autoimmune diseases, systemic vasculitis and childhood collagen diseases including lupus. 3/ To describe progressive characteristics and treatment of these patients in more detail. 4/ To further basic, clinical and epidemiological studies by creating a biobank and connections with other cohorts and registries 5/ To promote the assessment of medical practices and the application of national protocol recommendations for diagnosis and care.

Inclusion criteria	Patients included in the CEMARA database must have a diagnosis relevant to the label "juvenile arthritis" in the rare disease reference centre = inflammatory paediatric rheumatology diseases identified in the CEMARA thesaurus (and Orphanet thesaurus) belonging to one of the following 4 categories: juvenile idiopathic arthritis, other juvenile arthritis, paediatric autoinflammatory diseases, systemic diseases and paediatric vasculitis
<b>Population type</b>	
Age	Childhood (6 to 13 years) Adolescence (13 to 18 years)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	Multicentric cohort throughout France
<b>Data collection</b>	
<b>Dates</b>	
Date of first collection (YYYY or MM/YYYY)	05/2007
<b>Size of the database</b>	
Size of the database (number of individuals)	[1000-10 000[ individuals
Details of the number of individuals	1068
<b>Data</b>	

Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Direct physical measures Medical registration
Presence of a biobank	Yes
Contents of biobank	Serum Plasma DNA DNAc/RNAc
Details of biobank content	Serum bank, plasma bank, DNA bank, RNA (TEMPUS TUBES OR EQUIVALENT)
Health parameters studied	Health event/morbidity Health event/mortality
<b>Procedures</b>	
Data collection method	Interview: Direct input Clinical examinations: Direct input
Participant monitoring	Yes
Details on monitoring of participants	(Indefinite duration)
Links to administrative sources	Yes
Linked administrative sources (detail)	CépiDc
<b>Promotion and access</b>	
<b>Promotion</b>	
<b>Access</b>	
Dedicated website	<a href="https://cemara.org">https://cemara.org</a>
Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by academic teams. Contractual access. Data may not be used by industrial teams
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only