

# SAM - Severe Drug Allergy Physiopathology and Characterisation of Novel Diagnostic and Therapeutic Targets

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## General

### Identification

Detailed name Severe Drug Allergy Physiopathology and Characterisation of Novel Diagnostic and Therapeutic Targets

Sign or acronym SAM

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation --

### General Aspects

Medical area Study of allergies

Health determinants Genetic

### Scientific investigator(s) (Contact)

Name of the director Nicolas

Surname Jean-François

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Unit Equipe 14 Inserm U1111- CIRI "Immunologie de l'allergie cutanée et vaccination"

Organization INSERM - Institut National de la Santé et de la Recherche

Name of the director Berard

Surname	Frédéric
Collaborations	
Funding	
Funding status	Mixed
Details	AO HCL Action incitative 2009 INSERM/DHOS 2009
<b>Governance of the database</b>	
Sponsor(s) or organisation(s) responsible	INSERM - Institut National de la Santé et de la Recherche Médicale
Organisation status	Public
<b>Additional contact</b>	
<b>Main features</b>	
<b>Type of database</b>	
Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
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. All patients who attended CCR2A and agreed to be included in cohort. No randomisation or selection.
<b>Database objective</b>	
Main objective	To improve pathophysiological understanding of cutaneous Adverse Drug Reaction (cADRs) by clarifying the number and functional status of T lymphocytes (LT) CD8 + CTLs specific to medication. We wish to: i) confirm the involvement of CD8+ cells for different diseases; ii) understand why the same cell (CD8+) is responsible for different clinical forms of severity.
Inclusion criteria	Patient presenting with maculopapular rash (MPR), Drug Hypersensitivity Syndrome (DRESS) or Lyell's Syndrome (toxic epidermal necrolysis) (SJS/TEN)

caused by medication, diagnosed by referring physicians in the Rhône-Alpes Auvergne Centre de Compétences (CCR2A)

## Population type

Age  
Adulthood (19 to 24 years)  
Adulthood (25 to 44 years)  
Adulthood (45 to 64 years)

Population covered  
Sick population

Gender  
Male  
Woman

Geography area  
Regional

French regions covered by the database  
Auvergne Rhône-Alpes

Detail of the geography area  
Rhône-Alpes-Auvergne

## Data collection

### Dates

Date of first collection (YYYY or MM/YYYY)  
2009

### Size of the database

Size of the database (number of individuals)  
< 500 individuals

Details of the number of individuals  
102

### Data

Database activity  
Current data collection

Type of data collected  
Clinical data

Clinical data (detail)  
Direct physical measures  
Medical registration

Presence of a biobank  
Yes

Contents of biobank  
Whole blood  
Serum  
Blood cells isolated  
Fluids (saliva, urine, amniotic fluid, ?)

Tissues  
Others

Details of biobank content      Blood sample (30 mL heparin tube), Two skin biopsies (3 mm in diameter), one for damaged skin and one for healthy skin

Health parameters studied      Health event/morbidity  
Health event/mortality  
Health care consumption and services

Care consumption (detail)      Hospitalization  
Medical/paramedical consultation  
Medicines consumption

## Procedures

Data collection method      All cohort samples were collected by Allergobiotech (Headed up by Dr. Aurore Rozieres, INSERM U1111-CIRI/HCL).

Participant monitoring      Yes

Details on monitoring of participants      Systematic visit 3 months following reaction. Other follow-ups (6 months and 9 months) may be scheduled depending on the patient's condition and severity of reaction. A visit at 1 year is also systematic.

Links to administrative sources      No

## Promotion and access

### Promotion

### Access

Terms of data access (charter for data provision, format of data, availability delay)      Data from this cohort are accessible through scientific publications. If other researchers wish to access this data, a request must be made and data will be made available according to good clinical practice. Filtered "access request". No "open access".

Access to aggregated data      Access on specific project only

Access to individual data      Access on specific project only