

Nutrivigilance - Longitudinal study on general population : monitoring the safety of food supplements

Head :Vo Van-Regnault Gwenn

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General	
Identification	
Detailed name	Longitudinal study on general population : monitoring the safety of food supplements
Sign or acronym	Nutrivigilance
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL 1805396
General Aspects	
Medical area	General practice
Health determinants	Intoxication Nutrition
Scientific investigator(s) (Contact)	
Name of the director	Vo Van-Regnault
Surname	Gwenn
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Organization	Anses
Collaborations	
Participation in projects, networks and consortia	No
Funding	
Funding status	Public
Details	Anses (French agency for food, environmental

and occupational health & safety)

Governance of the database

Sponsor(s) or organisation(s) responsible Anses (French agency for food, environmental and occupational health & safety)

Organisation status Public

Presence of scientific or steering committees No

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details) Longitudinal study (except cohorts)

Database recruitment is carried out by an intermediary A selection of health care professionals
A selection of health institutions and services

Database recruitment is made on the basis of: Another treatment or procedure

Database recruitment is carried out as part of an interventional study No

Database objective

Main objective The aim is to monitor the safety of food supplements / food fortified with nutritional or physiological substances / novel foods / foods for particular diet under their actual conditions of use by identifying and analyzing the adverse effects that may be related to their consumption

Inclusion criteria All cases of adverse effects reported by a health professional (doctor, pharmacist, etc.)

Population type

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)
Adulthood (19 to 24 years)
Adulthood (25 to 44 years)

	Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	General population
Pathology	
Gender	Male Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	Declarations <4000 ; Declarants <1000 ; Products <2000
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
Declarative data (detail)	Internet self-questionnaire
Presence of a biobank	No
Health parameters studied	Others
Procedures	
Participant monitoring	No

Followed pathology

Links to administrative sources Yes

Promotion and access

Promotion

Access

Dedicated website <https://pro.anses.fr/nutrivigilance/>

Terms of data access (charter for data provision, format of data, availability delay) Upon a reasoned request to ANSES.

Access to aggregated data Access on specific project only

Access to individual data Access on specific project only