EVANESCO - Cohort Event monitoring of COVID-19 vAcciNE Safety in France using patient-reported outCOmes

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General

Identification

Detailed name	Cohort Event monitoring of COVID-19 vAcciNE Safety in France using patient-reported outCOmes
Sign or acronym	EVANESCO
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ID-RCB : 2020-A03554-35; CPP : 21.01.14.466.31

General Aspects

Medical area	Infectious diseases
Study in connection with Covid-19	Yes
Pathology (details)	Patient-reported adverse drug reactions following COVID-19 vaccination
Health determinants	Iatrogenic Medicine
Keywords	COVID-19, vaccines, adverse drug reactions

Scientific investigator(s) (Contact)

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Unit	Bordeaux PharmacoEpi (BPE) Research Platform - Inserm CIC1401

Organization	University of Bordeaux

Collaborations

Participation in projects, networks and consortia	Yes
Details	European consortium coordinated by Utrecht University, Netherlands; Participant Centres: Pharmacovigilance Centre LAREB, Netherlands; Federal Agency for Medicines and Health Products, Belgium; Luxembourg Institute of Health, Luxembourg; University of Verona, Italy; University of Bordeaux, France; DSRU, England; Paul Ehrlich Institute, Germany; HALMED, Croatia

Funding

Funding status	Public
Details	EMA and the French Ministry of Health

Governance of the database

Sponsor(s) or organisation(s) responsible	University of Bordeaux, Bordeaux PharmacoEpi (BPE) Research Platform Inserm CIC1401
Organisation status	Both
Presence of scientific or steering committees	No

Additional contact

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Unit	Bordeaux PharmacoEpi (BPE) Research Platform - Inserm CIC1401
Organization	University of Bordeaux

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
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.	Recruitment of participants at vaccination centres and pharmacies with collection of primary data directly from individuals vaccinated against COVID-19 via a dedicated secure online application.

Database objective	
Main objective	To generate incidence rates of patient-reported Adverse Drug Reaction (ADR) of brand specific COVID-19 vaccination in France, in near real time.
Inclusion criteria	- To describe ADR incidence rates according to brand of vaccine and to specific populations such as, pregnant women, patients with severe co-morbidities (e.g., frail, vaccinees with auto-immune diseases), elderly, children, patients having recently received other vaccines; - To detect potential novel safety signals; - To identify possible risk factors for ADR.

Population type	
Age	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	Vaccination centers at the national level and pharmacies in Bordeaux agreeing to provide information on the study to those vaccinated.

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2021
Date of last collection (YYYY or MM/YYYY)	2023

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	6,640 vaccinated individuals in France

Data

Database activity	Current data collection
Type of data collected	Declarative data
Declarative data (detail)	Internet self-questionnaire
Details of collected declarative data	Date of birth, gender, weight, height, name of vaccine, batch number, vaccination date, place of vaccination, medical history including previous COVID-19 infection, pregnancy, occupation if related to health care, medication taken, adverse reactions occurring after vaccination (type, date, duration, medication taken, examinations performed, seriousness, outcome, impact on daily life), COVID-19 infection after vaccination
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Others
Other (detail)	Adverse drug reactions occurring after vaccination against COVID-19

Procedures

Data collection method	Data collection via a dedicated secure online application, with data entry by the vaccinated individuals.
Classifications used	MedDRA coding of adverse reactions
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the participant (mail, e-mail, telephone etc.)
Details on monitoring of participants	Vaccinated individuals eceiving one dose of vaccine, 1st dose or booster dose, followed for 3 to 6 months via self-administered questionnaires to be completed by internet at inclusion, 1, 2, 6, 8 weeks, then 3 and 6 months, if applicable, after the start of the vaccination
Links to administrative sources	Yes
Linked administrative sources (detail)	SNDS, SI-Vaccine COVID and SI-DEP with 2 years of history and 1 year of follow-up: probabilistic chaining

Promotion and access

Promotion

Access