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

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## Général

### Identification

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|---|---|
| Nom détaillé | Cohort Event monitoring of COVID-19 vAcciNE Safety in France using patient-reported outCOmes |
| Sigle ou acronyme | EVANESCO |
| Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.) | ID-RCB : 2020-A03554-35; CPP : 21.01.14.466.31 |

### Thématiques générales

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|---|---|
| Domaine médical | Infectious diseases |
| Etude en lien avec la Covid-19 | Yes |
| Pathologie, précisions | Patient-reported adverse drug reactions following COVID-19 vaccination |
| Déterminants de santé | Iatrogenic<br>Medicine |
| Mots-clés | COVID-19, vaccines, adverse drug reactions |

### Responsable(s) scientifique(s)

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| Nom du responsable | Thurin |
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| Laboratoire | Bordeaux PharmacoEpi (BPE) Research Platform - Inserm CIC1401 |
| Organisme | University of Bordeaux |

### Collaborations

| | |
|---|---|
| Participation à des projets, des réseaux, des consortiums | Yes |
| Précisions | 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 |

## Financements

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| Financements | Public |
| Précisions | EMA and the French Ministry of Health |

## Gouvernance de la base de données

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| Organisation(s) responsable(s) ou promoteur | University of Bordeaux, Bordeaux PharmacoEpi (BPE) Research Platform Inserm CIC1401 |
| Statut de l'organisation | Mixte |
| Existence de comités scientifique ou de pilotage | No |

## Contact(s) supplémentaire(s)

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# Caractéristiques

## Type de base de données

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|---|---|
| Type de base de données | Study databases |
| Base de données issues d'enquêtes, précisions | Cohort study |
| Origine du recrutement des participants | A selection of health institutions and services |
| Critère de sélection des participants | Medication(s) taken |
| Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle | No |
| Informations complémentaires concernant la constitution de l'échantillon | 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. |

## Objectif de la base de données

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| Objectif principal | To generate incidence rates of patient-reported Adverse Drug Reaction (ADR) of brand specific COVID-19 vaccination in France, in near real time. |
| Critères d'inclusion | - 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;<br>- To detect potential novel safety signals;<br>- To identify possible risk factors for ADR. |

## Type de population

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| Age | Childhood (6 to 13 years)<br>Adolescence (13 to 18 years)<br>Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more) |
| Population concernée | General population |
| Pathologie | |
| Sexe | Male<br>Woman |

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| Champ géographique | National |
| Détail du champ géographique | Vaccination centers at the national level and pharmacies in Bordeaux agreeing to provide information on the study to those vaccinated. |

## Collecte

### Dates

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| Année du premier recueil | 2021 |
| Année du dernier recueil | 2023 |

### Taille de la base de données

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| Taille de la base de données (en nombre d'individus) | [1000-10 000[ individuals |
| Détail du nombre d'individus | 6,640 vaccinated individuals in France |

### Données

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|---|---|
| Activité de la base | Current data collection |
| Type de données recueillies | Declarative data |
| Données déclaratives, précisions | Internet self-questionnaire |
| Détail des données déclaratives recueillies | 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 |
| Existence d'une biothèque | No |
| Paramètres de santé étudiés | Health event/morbidity<br>Health event/mortality<br>Others |
| Autres, précisions | Adverse drug reactions occurring after vaccination against COVID-19 |

### Modalités

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| Mode de recueil des données | Data collection via a dedicated secure online |

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| | application, with data entry by the vaccinated individuals. |
| Nomenclatures employées | MedDRA coding of adverse reactions |
| Suivi des participants | Yes |
| Modalités de suivi des participants | Monitoring by contact with the participant (mail, e-mail, telephone etc.) |
| Détail du suivi | 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 |
| Appariement avec des sources administratives | Yes |
| Sources administratives appariées, précisions | SNDS, SI-Vaccine COVID and SI-DEP with 2 years of history and 1 year of follow-up: probabilistic chaining |

## Valorisation et accès

### Valorisation et accès

### Accès