

# Incidence, prevalence and burden of Dry Eye disease in France (IDEA)

**First published:** 03/05/2019

**Last updated:** 24/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS29618

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### Study ID

49825

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### DARWIN EU® study

No

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### Study countries

 France

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### Study description

Dry Eye Disease (DED) is a multifactorial disorder due to excessive tear evaporation and/or insufficient tear production. The multiplicity of criteria (signs, symptoms, feelings) potentially used to define DED makes the

assessment of DED prevalence complex (5 to 50% according to the Dry Eye Workshop II (DEWS II) of the Tear Film and Ocular Surface (TFOS) Society). Treatment of DED mainly relies on artificial tears and lifestyle advice for mild and medium stage. In some severe cases pharmacological therapy such as cyclosporine or lacrimal punctual plugs can be necessary. In France, most of the tears substitutes are reimbursed (11.3 millions of packs in 2015). All healthcare consumption regardless physician specialities would be very helpful to fully assess DED burden in France. In the context of the European Marketing Authorization Application for a new treatment for DED, Shire wants to better understand the burden of DED, through healthcare consumption regardless physician. This project is designed to estimate the prevalence and the incidence of the disease in France, as well as assess baseline characteristics of patients, treatment pattern, disease evolution, healthcare resource use and costs using EGB, a 1/97 permanent representative sample of the French nationwide claims database (SNDS). Patients with at least 3 dispensing of artificial tears over a 6-month period or one dispensing of ocular cyclosporine in 2014-2015 will be included and followed for 2 years. The French health technology assessment agency (Haute Autorité de Santé - HAS) estimates the population with DED between 3.5 and 4.7 millions of subjects in France, including 1 million with moderate or severe disease, that represents approximately 10 000 subjects expected in this EGB study. The study was cancelled at the request of the sponsor, SHIRE. The drug of interest was transferred to another pharmaceutical company which decided not to continue the associated study. Study final date: 2019/10/21

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### **Study status**

Finalised

## Research institutions and networks

# Institutions

## Bordeaux PharmacoEpi, University of Bordeaux

 France

**First published:** 07/02/2023

**Last updated:** 08/12/2025

**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

Not-for-profit

ENCePP partner

## Contact details

### Study institution contact

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Study contact

[plateforme.bpe@u-bordeaux.fr](mailto:plateforme.bpe@u-bordeaux.fr)

### Primary lead investigator

Patrick Blin

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 14/05/2018

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**Study start date**

Planned: 30/05/2019

Actual: 21/10/2019

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**Data analysis start date**

Planned: 30/05/2019

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**Date of final study report**

Planned: 30/09/2019

Actual: 21/10/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Shire

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

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## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

Healthcare resource utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The main objective is to estimate the DED prevalence and incidence in France in 2014 and 2015.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medical condition to be studied**

Dry eye

## Population studied

## **Short description of the study population**

Subjects with dry eye disease (DED) identified from the French nationwide claims database (SNDS).

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### **Age groups**

- Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with dry eye disease

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### **Estimated number of subjects**

10000

## **Study design details**

### **Data analysis plan**

The following analyses will be performed:- A flow chart and an attrition table depicting the number of patients identified in the database- Description of

patient baseline demographics and clinical characteristics, according to prevalent/incident status and DED severity level- Estimation of the annual prevalence and incidence of DED in 2014 and 2015 in the French population. Prevalence by DED severity level will also be computed- Description of treatment pattern at the index date (stratified on incident/prevalent status and DED severity level), and during the follow-up period (stratified on DED severity only)- Description of the disease evolution (switch between DED severity levels over the follow-up period and duration of severity stages)- Description of healthcare resource use and costs for one and two years from the National Health Insurance perspective and for the collective perspective stratified by DED severity level

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### Data sources

#### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

### Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No