# Observational, Cross-Sectional Post-Authorisation Safety Study to Assess Healthcare Provider Awareness of Risks Related to Sofosbuvir and Ledipasvir/Sofosbuvir (EU HVN SOF Survey Study)

**First published:** 08/09/2016

**Last updated:** 31/03/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS15103

**Study ID**

20772

**DARWIN EU® study**

No

**Study countries**

- Bulgaria
- Denmark
- France
- Germany
- Hungary
- Spain
- United Kingdom

**Study description**

Investigate healthcare provider awareness of the risk of clinically significant arrhythmias when sofosbuvir (in combination with daclatasvir or simeprevir) or ledipasvir/sofosbuvir is prescribed concurrently with amiodarone, and determine perceptions of co-medication frequency, reported changes in prescribing behaviour, and reported approaches to patient monitoring following dissemination of a direct healthcare professional communication.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Gilead Sciences

**First published:** 12/02/2024

**Last updated:** 12/02/2024

Institution | Pharmaceutical company

Multiple centres: 301 centres are involved in the study

## Contact details

**Study institution contact**

Funmi Sserunkuma funmi.sserunkuma@gilead.com

**Study contact**

funmi.sserunkuma@gilead.com

**Primary lead investigator**

Funmi Sserunkuma

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 05/01/2016

Actual: 05/01/2016

---

**Study start date**

Planned: 01/12/2016

Actual: 25/11/2016

---

**Data analysis start date**

Planned: 15/03/2017

Actual: 10/03/2017

**Date of final study report**

Planned: 01/09/2017

Actual: 25/08/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Gilead Sciences Europe

## Study protocol

1.2-Prot GS-EU-337-2030 FINAL SIGNED.pdf (908.64 KB)

## Regulatory

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

No

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

EU RMP category 3 (required)

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Drug utilisation

**Data collection methods:**

Primary data collection

---

**Main study objective:**

The primary objective of this study is as follows: Determine the proportion of healthcare providers aware of the risk of clinically significant arrhythmias when SOF (in combination with DCV or SMV) or LDV/SOF is prescribed concurrently with amiodarone.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medicinal product name**

HARVONI

SOVALDI

**Medical condition to be studied**

Chronic hepatitis C

# Population studied

**Short description of the study population**

All healthcare providers (including gastroenterologists, hepatologists, infectious disease physicians, cardiologists, general practitioners/internists, and specialty and hospital pharmacists) responsible for the treatment of Chronic hepatitis C patients in Europe.

**Age groups**

- 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)

**Special population of interest**

Hepatic impaired

**Estimated number of subjects**

200

# Study design details

**Outcomes**

The risk evaluation and mitigation strategy will be considered effective if the majority of respondents demonstrate they are aware of the key risks communicated.

---

**Data analysis plan**

Data from the survey questionnaire will be summarized descriptively (counts, ranges, proportions) overall, as well as by country and provider specialty where sample size allows. For the primary objective, frequency point-estimates with two-sided 95% confidence intervals(CIs) using the binomial distribution (Wald or Clopper-Pearson method, as appropriate) will be constructed to describe the proportion of physicians aware of the specified risk. The secondary objectives will produce categorical data which will be summarized by frequencydistributions.

## Documents

**Study results**

GS-EU-337-2030+ABSTRACT+Clinical+Study+Report.pdf (102.32 KB)

---

# 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)**

Other

**Data sources (types), other**

Survey involving primary data collection

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown