

# DAA-PASS: A Post-Authorisation Safety Study of Early Recurrence of Hepatocellular Carcinoma in HCV-Infected Patients after Direct-Acting Antiviral Therapy

**First published:** 01/03/2018

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS22896

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### Study ID

47600

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### DARWIN EU® study

No

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### Study countries

 France

 Germany

 Italy

 Spain

 United States

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### **Study description**

This prospective, observational study will estimate the risk of early HCC recurrence associated with DAA therapy exposure relative to no DAA therapy exposure during routine clinical care of HCV-infected patients with previous successfully treated HCC using a prospective cohort from TARGET HCC.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Multiple centres: 60 centres are involved in the study

## Contact details

### **Study institution contact**

Andrea Mospan [amospan@targetpharmasolutions.com](mailto:amospan@targetpharmasolutions.com)

**Study contact**

[amospan@targetpharmasolutions.com](mailto:amospan@targetpharmasolutions.com)

### **Primary lead investigator**

Andrea Mospan

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 12/02/2018

Actual: 12/02/2018

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### Study start date

Planned: 05/03/2018

Actual: 29/03/2018

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### Date of final study report

Planned: 31/12/2021

Actual: 15/12/2021

## Sources of funding

- Other

## More details on funding

TARGET PharmaSolutions, Inc.

## Study protocol

[TARGET-HCC\\_DAA-PASS\\_Protocol\\_v3\\_3\\_06Jun2018\\_Final.pdf](#) (967.39 KB)

[TARGET-HCC\\_DAA-PASS\\_Protocol\\_v6.0.pdf](#) (1.26 MB)

## Regulatory

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

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

Disease /health condition

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Data collection methods:**

Secondary use of data

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#### **Main study objective:**

Estimate the risk of early HCC recurrence associated with DAA therapy exposure relative to no DAA therapy exposure in the prospective DAA-PASS

cohort.

## Study Design

### **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Observational study

## Study drug and medical condition

### **Study drug International non-proprietary name (INN) or common name**

SOFOSBUVIR

VELPATASVIR

VOXILAPREVIR

ELBASVIR

GRAZOPREVIR

GLECAPREVIR

PIBRENTASVIR

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### **Anatomical Therapeutic Chemical (ATC) code**

(J05AX14) daclatasvir

daclatasvir

(J05AX16) dasabuvir

dasabuvir

(J05AX67) ombitasvir, paritaprevir and ritonavir

ombitasvir, paritaprevir and ritonavir

(J05AE14) simeprevir

simeprevir

(J05AX15) sofosbuvir

sofosbuvir

(J05AX65) sofosbuvir and ledipasvir

sofosbuvir and ledipasvir

(J05AX69) sofosbuvir and velpatasvir

sofosbuvir and velpatasvir

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### **Medical condition to be studied**

Hepatocellular carcinoma

## Population studied

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

Prospective Cohort

The prospective DAA-PASS cohort will include a subset of HCV RNA positive participants in the TARGET-HCC study who meet entry criteria including hepatitis C (with no prior history of DAA therapy) and newly diagnosed Barcelona Clinic Liver Cancer (BCLC) Stage A HCC. Participants will be enrolled in the countries participating in TARGET-HCC which will include the United States (US), France, Germany, Italy, and Spain.

Historical Cohort

The historical cohort will be derived from the ITA.LI.CA database, which includes data on all consecutive patients with HCC who were managed within participating centers in Italy. The historical cohort will include patients from the ITA.LI.CA database who have active HCV infection who were not treated for HCV (IFN-based or DAA-based regimens) during the followup period, with initial HCC

diagnosis BCLC Stage A, and subsequent successful treatment of HCC with curative therapy.

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### **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)
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### **Special population of interest**

Hepatic impaired

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### **Estimated number of subjects**

35

## Study design details

### **Outcomes**

Time to recurrence of HCC, A. Number of events (early HCC recurrence)

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### **Data analysis plan**

risk estimation

## Documents

### **Study results**

[DAA-PASS CSR Abstract 2.0\\_Final\\_Redacted.pdf](#) (468.72 KB)

[DAA-PASS CSR Abstract Final v5.0\\_16 Dec 2021.pdf](#) (92.22 KB)

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## 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

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### Data sources (types), other

TARGET-HCC

## 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