Unidad de Ensayos Clínicos
Agencia Española del Medicamento y Productos Sanitarios (AEMPS)
Parque Empresarial Las Mercedes, Edificio 8
C. Campezo, 1
28922 Madrid

European Medicines Agency (EMA)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject	To state reasons for the trial premature interruption
Study Title	PILOT STUDY TO EVALUATE THE EFFECTS OF PARITAPREVIR/r, DASABUVIR AND OMBITASVIR ON LIVER FUNCTION AND SYSTEMIC HEMODYNAMIC IN PATIENTS WITH DECOMPENSATED HCV-CIRRHOSIS
Protocol code	DECIPHER-3D
EudraCT Number	2015-003152-43
Product	Paritaprevir/ritonavir, Ombitasvir, Dasabuvir y Ribavirina
Sponsor	Fundación Clínic Barcelona
Trial end	17th February 2017

4th September 2025

Dear sir/madam,

The trial was a single centre study conducted in Spain.

This trial was approved by the Spanish authorities but never started.

This study was not a Low Intervention Trial.

The active site was: Hospital Clínic de Barcelona, C/ Villarroel 170, 08036 (Barcelona).

Harmonised Protocol (version 1.0, 22/06/2015):

Member State	Date of approval		
	National Competent Authority	Ethics Committee	Name of Ethics Committee
SPAIN	04/02/2016	02/09/2015	CEIC Hospital Clinic de Barcelona

Declaration

The sponsor, Fundació de Recerca Clínic Barcelona- Institut d'Investigacions Biomèdiques August Pi i Sunyer (FRCB-IDIBAPS), hereby declares that the clinical trial with EudraCT Number 2015-003152-43, ended prematurely on 24th February 2022.

The study did not start because The sponsor considered that initiating the study would pose an unacceptable risk in light of the information note published by the AEMPS on December 23, 2015, which advises against the use of Viekirax in patients with moderate hepatic impairment (Child-Pugh B). As this population represented the entirety of the intended study participants, the trial was not initiated.

Please do not hesitate in contacting us should you need further information.

Yours faithfully,

Sara Campos
Application Submitter CTU CLINIC