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	Phase 3b, single arm, single site simplification study with dual therapy including 3TC (300 mg QD) plus Raltegravir (1200 mg QD) in virologically suppressed HIV-1 infected atients experiencing inconvenience, toxicity, negative impact on co-morbidities or risk of drug-drug interactions with their current regimen. RALAM-II study
Protocol code	RALAM II
EudraCT Number	2017-000985-31
Product	Raltegravir, Lamivudine
Sponsor	Fundació Clinic per a la Recerca Biomédica
Trial end	25th June 2020

07, March, 2025

Dear sir/madam,

The trial was a single centre study conducted in Spain.

This trial was approved by the Spanish authorities but ended prematurely.

This study was not a Low Intervention Trial.

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

Harmonised Protocol (version 1.2, 04/05/2017):

Member State	Date of approval		
	National Competent Authority	Ethics Committee	Name of Ethics Committee
SPAIN	04/10/2017	27/09/2017	CEIm Hospital Clínic de Barcelona

Declaration

The sponsor, Fundació de Recerca Clínic Barcelona, hereby declares that the clinical trial with EudraCT Number 2017-000985-31 ended prematurely on 25th June 2020.

The reason for the premature termination was the failure to reach the required number of participants.

Consequently, it was not possible to conduct an evaluation of results nor to determine the overall benefit/risk profile of the investigational medicinal product.

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

Yours faithfully,

Sara Campos
Application Submitter CTU CLINIC