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	Study about the response to the administration of a third dose of mRNA-1273 vaccine (COVID19 vaccine Moderna) in renal transplants with immunological failure initial to vaccination
Protocol code	VAX-TRES
EudraCT Number	2021-002356-37
Product	VACUNA mRNA-1273 (COVID19 Vaccine Moderna)
Sponsor	Fundació Clinic per a la Recerca Biomèdica (FCRB)
Trial end	24th February 2022

27th March 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 1.1, 24/07/2021):

Member State	Date of approval		
	National Competent Authority	Ethics Committee	Name of Ethics Committee
SPAIN	22/09/2021	15/09/2021	CEIm Hospital Clínic 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 2021-002356-37, ended prematurely on 24th February 2022.

The study did not start due to a lack of candidates.

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

Yours faithfully,

Sara Campos
Application Submitter CTU CLINIC