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	Subjects with subjective cognitive decline: 18F-Florbetaben Positrón Emission Tomography Study
Protocol code	Euro-SCD-FBB2
EudraCT Number	2016-003451-30
Product	PET-tracer 18F-FlorbetabenNeuraceq® 300 MBq/ml solution for injection
Sponsor	Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS)
Trial end	28th February 2019

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 2.0, 12th January 2017):

Member State	Date of approval		
	National Competent Authority	Ethics Committee	Name of Ethics Committee
SPAIN	14/02/2017	03/02/2017	CEIm Hospital Clínic de Barcelona

Declaration

The sponsor, Fundació de Recerca Clínic Barcelona- Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), hereby declares that the clinical trial with EudraCT Number 2016-003451-30 ended prematurely on 28th February 2019.

The trial never started due to the inability to distribute the study contrast agent (florbetaben). Therefore, it was not administered to any patients.

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

Yours faithfully,

Sara Campos
Application Submitter CTU CLINIC