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	EudraCT- Submission note
Protocol Study Title	Antithrombotic therapy after left atrial appendage occlusion: double antiplatelet therapy vs. Apixaban
Article Study Title	Low-Dose Direct Oral Anticoagulation vs Dual Antiplatelet Therapy After Left Atrial Appendage Occlusion The ADALA Randomized Clinical Trial
Protocol code	ADALA
EudraCT Number	2018-001013-32
Product	APIXABAN
Sponsor	Fundació de Recerca Clínic Barcelona – Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS)
Trial end	31st December 2023

12nd December 2025

To Whom It May Concern,

The sponsor, Fundació de Recerca Clínic Barcelona- Institut d'Investigacions Biomèdiques August Pi i Sunyer (FRCB-IDIBAPS), hereby submit the attached article titled:
"Low-Dose Direct Oral Anticoagulation vs Dual Antiplatelet. Therapy After Left Atrial Appendage Occlusion. The ADALA Randomized Clinical Trial".
Published online August 7, 2024 in **JAMA Cardiology**. doi:10.1001/jamacardio.2024.2335, as the summary of results for the ADALA Trial (EudraCT Number: 2018-001013-32).

This article contains all relevant information required by EudraCT, including:
- Study objectives and design
- Patient population and inclusion/exclusion criteria
- Treatment arms and interventions
- Primary and secondary outcomes
- Statistical analysis and results
- Safety data and adverse events
- Conclusions and clinical implications

The sponsor confirms that the clinical trial with EudraCT Number 2018-001013-32, was prematurely terminated when only 60%of the estimated sample size had been included due to lower recruitment rate than anticipated due to the COVID-19 pandemic, on 31st December 2023.

In accordance with EudraCT guidance, when a study is prematurely ended and does not meet its planned enrollment, sponsors may submit a summary attachment in lieu of the full data set. The attached article is a peer-reviewed publication that meets the standards outlined in Annex 1 of the ICH E3 guideline.

We confirm that we hold the rights to submit this document and that it accurately reflects the outcomes of the clinical trial ADALA (EudraCT Number: 2018-001013-32).

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

Sincerely,

Sara Campos
Application Submitter CTU CLINIC
FRCB – IDIBAPS