

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	Treatment for Moderate/Severe COVID-19 in a Fragile and Vulnerable Population, Admitted to a Geriatric Hospital Unit or in a Transicional Care Center
Article Study Title	FRAGILE-COLCOVID19: A Clinical Trial Based on Early Administration of an Oral Combination of Colchicine and Prednisone in Elderly Patients with COVID-19 in Geriatric Facilities
Protocol code	FRAGILE-COLCOVID19
EudraCT Number	2020-002462-14
Product	Colchicine, Prednisone tablet
Sponsor	Fundació de Recerca Clínic Barcelona – Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS)
Trial end	31st May 2021

17th November 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: "FRAGILE-COLCOVID19: A Clinical Trial Based on Early Administration of an Oral Combination of Colchicine and Prednisone in Elderly Patients with COVID-19 in Geriatric Facilities" published in Clinical Drug Investigation (2022) 42:949–964, as the summary of results for the FRAGILE-COLCOVID19 (EudraCT Number: 2020-002462-14).

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 2020-002462-14, ended prematurely, due to low recruitment rate on 31st May 2021.

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 FRAGILE-COLCOVID19 (EudraCT Number: 2020-002462-14).

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

Sincerely,

Sara Campos
Application Submitter CTU CLINIC
FRCB – IDIBAPS