**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

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|---|---|
| Subject | EudraCT- Submission note |
| Protocol Study Title | Albumin administration in the prevention of hepatorenal syndrome and death in patients with cirrhosis, bacterial infections other than spontaneous bacterial peritonitis and high risk of hospital mortality |
| Article Study Title | Efficacy of Albumin Treatment for Patients with Cirrhosis and Infections Unrelated to Spontaneous Bacterial Peritonitis |
| Protocol code | INFECIR2 |
| EudraCT Number | 2013-002416-27 |
| Product | Albumin (Albutein 20%, Instituto Grifols) |
| Sponsor | Fundació de Recerca Clínic Barcelona – Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS) |
| Trial end | 17th February 2017 |

16th September 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: "Efficacy of Albumin Treatment for Patients with Cirrhosis and Infections Unrelated to Spontaneous Bacterial Peritonitis" published in Clinical Gastroenterology and Hepatology (2020;18:963–973), as the summary of results for the INFECIR-2 (EudraCT Number: 2013-002416-27).

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 2013-002416-27, ended prematurely, due to low recruitment rate and expiration of the study drug, on 17th February 2017.

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 INFECIR-2 (EudraCT Number 2013-002416-27)

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

Sincerely,

Sara Campos
Application Submitter CTU CLINIC