



Fecha: 28-10-2022

Asunto: Justification document for unposted
results of 2013-000915-26

European Medicines Agency
Orlyplein 24,
1043 DP Amsterdam,
The Netherlands

Dear EudraCT team,

Re: EudraCT - EudraCT results' document to be posted

Sponsor: Red Andaluza de Diseño y Traslación en Terapias Avanzadas (former Iniciativa Andaluza en Terapias Avanzadas) – Fundación Progreso y Salud

In relation to the clinical trial CMMo-OCC-2012, there are currently three patients in safety monitoring, finishing the last of these three patients in July 2023.

The recruitment of this trial was temporarily interrupted in April 2019 due to the detection of deviations and serious failures by the participating centre, Hospital Reina Sofía. Subsequently, after the implementation of various urgent measures, such as the constitution of an Independent Committee on Safety and Data Monitoring (ICSDM) to assess the relevance of continuing or not the clinical trial, and the adoption of a new amendment, the recruitment was resumed in January 2020. Despite this, due to the low recruitment rate that made it impossible to reach the expected sample size within a reasonable time (only 28 out of the 66 expected patients were recruited), early termination was decided and notified the 1st of November 2021.

EudraCT Number	Trial code - Full title of the trial	Sponsor name
2013-000915-26	CMMo-OCC-2012 - Clinical Trial Phase III single-center, open-label efficacy of intracoronary infusion of bone marrow mononuclear cells in patients with occlusion Autologous chronic coronary revascularization and ventricular dysfunction previously	Red Andaluza de Diseño y Traslación en Terapias Avanzadas (former Iniciativa Andaluza en Terapias Avanzadas) – Fundación Progreso y Salud

Fundación Progreso y Salud M.P.

Parque Científico y Tecnológico Cartuja

Avda. Américo Vespucio 15 • Edificio S-2 • 2ª Pta. 41092 Seville (Spain)

Tel.: +34 955 048 366 • Fax: +34 955 267 002