

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	Mapping Sentinel Lymph Node in Initial Stages of Ovarian Cancer (MELISA)
Article Study Title	Mapping sentinel lymph nodes in early-stage ovarian cancer (MELISA) trial - a further step towards lymphadenectomy replacement
Protocol code	MELISA
EudraCT Number	2020-005546-42
Product	Radiotracer (99mTc-labelled colloid) and indocyanine green (ICG)
Sponsor	Fundació de Recerca Clínic Barcelona – Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS)
Trial end	1st March 2023

27th April 2026

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: "Mapping sentinel lymph nodes in early-stage ovarian cancer (MELISA) trial - a further step towards lymphadenectomy replacement". Published online December, 2023 in **Gynecologic Oncology**, <https://doi.org/10.1016/j.ygyno.2023.11.007>, as the summary of results for the MELISA Trial (EudraCT Number: 2020-005546-42).

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 MELISA (EudraCT Number 2020-005546-42, was completed after the inclusion of 30 subjects, although the planned sample size of 62 participants was not reached.

In accordance with EudraCT guidance, for single-arm, non-randomised exploratory clinical trials, results may be submitted as a summary attachment when the structure of a full data set is not applicable. The results of this study are therefore reported in aggregated form. The attached article is a peer-reviewed publication that adequately reports the study design, methodology, results and safety outcomes, in line with the principles outlined in Annex I of the ICH E3 guideline.

The Sponsor confirms that it holds the rights to submit this document and that the attached publication accurately reflects the outcomes of the MELISA clinical trial.

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

Sincerely,

Sara Campos
Application Submitter CTU CLINIC
FRCB – IDIBAPS