

D1.3 IDMC feedback

WPI. Project coordination and governance



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Document History

Version	Date	Description
V0.1	29 Nov 2025	Draft
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1. Abstract

This deliverable provides with the feedback from the EORTC Independent Data Monitoring Committee (IDMC).

According to its standard operating procedures, EORTC has set up an IDMC to review the risk-benefit ratio in the STRASS2 clinical trial, and make sure that patients are not exposed to unnecessary or unreasonable risks. The IDMC will also assess the study for futility.

The EORTC's IDMC reviewed the STRASS2 clinical trial including the STREXIT2 arm in May 2025. The IDMC recommended to continue the study. The IDMC recommended some modifications to the STRASS2 protocol regarding endpoint definition and the statistical analyse plan. Those changes will not affect STREXIT2.

The formal feedback of the IDMC is part of this deliverable.



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03 June 2025

EORTC-1809-STBSG

A randomized phase III study of neoadjuvant chemotherapy followed by surgery versus surgery alone for patients with High Risk RetroPeritoneal Sarcoma (STRASS 2)

Objectives of the review:

This review corresponds to the first planned per protocol interim analysis for futility.

In addition, the study team wishes the IDMC to review the accumulated data and asks whether the study can continue as it is.

Recommendations

The IDMC recommends to continue the study.

1. The IDMC recommends to amend the study protocol by modifying the definition of the primary endpoint: the criteria "Tumour becoming non-resectable / operability criteria not satisfied" should not be considered as an event for the primary endpoint if the patient was successfully operated (R0/R1 resection).
2. The IDMC recommends to write a statistical analysis plan separate from the protocol and conduct the formal interim futility analysis once the required 56 events are reached according to the modified definition of the primary endpoint.
The IDMC expects to receive the short futility interim analysis report (a full report is not required) when the number of events are available to determine whether the trial should continue.

Yours sincerely,

Emiliano Calvo
IDMC Chairman
START Madrid, ES
On behalf of the EORTC 1809 IDMC

Signed by:

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Signing Time: 03 June 2025 | 14:45:46 CEST
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