

D2.1 Study initiation package

WP2: Clinical trial



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Document History

Version	Date	Description
V0.1	29 May 2024	Draft
V1.0	29 May 2024	Final version
V1.1	14 Oct 2024	Revised version as requested by EU
V1.2	20 March 2026	Revised version with latest authorities approvals



Abstract

STREXIT2 is an observational arm added to the ongoing STRASS2 clinical trial. The STRASS2 clinical trial protocol was amended (substantial modification) to incorporate STREXIT2.

This deliverable aims to document 1) the authorization of the amendment to the STRASS2 clinical trial in Europe 2) the authorization of the 1st clinical site under the amended protocol by Spanish authorities. 3) the latest version of the protocol and evidence for its approval.

As study sponsor, the EORTC declares that all clinical studies used in STREXIT2 have been duly approved as such as they could have been legally carried out in the EU.

The allocated EU CT number to the STRASS2 clinical trial is 2019-003543-30 - 2023-505261-84-00 and NCT04031677 in the US NIH Library of Medicine database (ClinicalTrials.gov).

Deliverable content:

D2.1 is the compilation of the following documents:

- STRASS2 protocol amended for adding STREXIT2 arm (version 6.1, October 2023).
- STRASS2 protocol latest amendment (version 8, July 2025).
- Documentation of the approval of each protocol version according to the Clinical Trial Regulation.
 - Part I assessment report
 - Part I conclusion
 - Part I conclusion from participating countries
 - Part II conclusion from participating countries

