

PROGNOSIS IMPROVEMENT OF UNPROVOKED VENOUS THROMBOEMBOLISM USING PERSONALIZED ANTICOAGULANT THERAPY



HORIZON-HLTH-2022-TOOL-11-01 Project 101095698

NEWSLETTER N°4

JULY 2025

WELCOME to the MORPHEUS newsletter!

This is the fourth newsletter since the start of the project! Hereby the latest news on the consortium!

MORPHEUS ALL WPs MEETINGS

- Latest meeting: 07-JULY-2025
- Next meeting: 13-OCT-2025 via Teams.

MORPHEUS GENERAL ASSEMBLY MEETINGS

- Latest meeting: 7-APR-2025
- Next meeting: 15-SEP-2025 in Paris.

LATEST ACHIEVEMENTS

- WP2 and ETHER Study:
 - All SIVs performed in France and SIVs perfomed in Geneva (Switzerland), Madrid (Spain) and A Coruna (Spain)
 - All centres allowed to include in France except AP-HP, and inclusions allowed in Geneva, Madrid and A Coruna
 - CTA under signature in Poland and under discussion in other countries
 - First meeting of the TSC on June, 2nd
- WP2 and Merged cohorts: Data from the merged French cohort sent to the biostatistics team.
- WP3: 24 new molecular biomarkers, including certain proteins which are currently being measured in MARTHA samples and will subsequently be measured in EDITH samples
- WP4: Anthropo-morpheus submitted for a first publication
- WP5: Construction of TDMI still in progress and 1st test with clinicians
- WP6: authorship rules and dissemination plan updated
- WP7: 3rd meeting on June 24th
- EAB: 3rd meeting on May, 12th.

DELIVERABLES

- What has been recently submitted?
 - D2.4: Blank eCRF of merging cohort study
 - D3.1 Validated biological biomarkers
- What is upcoming?
- Identified relevant socio-anthropological markers to inform TDMI tool (WP4) M16 / 31-MAR-2025 delayed to M19 / 30-JUNE-2025
- Papers published/submitted on patient's preference and experience(WP4) M16 / 31-MAR-2025 delayed to M19 / 30-JUNE-2025 then 31-JULY-2025
- Qualitative studies report on <u>statut</u> of posting results (WP4) M20 / <u>31-JUL-2025</u>
- Derived scores from merged cohorts (WP5) M20 / 31-JUL-2025 delayed to M23 / 31-OCT-2025
- Qualitative <u>study</u> "ETHNO-MORPHEUS" <u>study</u> initiation packages (WP4) M6 / <u>31-MAY-2024 delayed to</u> M23 / <u>31-OCT-2025</u>
- Database on biobank for merged cohorts (WP3) M18 / 31-MAY-2025 delayed to M24 / 30-NOV-2025
- Validated PK/PD biomarkers (WP3) M18 / 31-MAY-2025 delayed to M24 / 30-NOV-2025
- Validated imaging biomarkers (WP3) M18 / 31-MAY-2025 delayed to M24 / 30-NOV-2025
- Short report for updating on policy's objectives, implementation, potential impact (WP1) M24 / 30-NOV-2025
- Midterm recruitment report (WP2) M24 / 30-NOV-2025
- Validated TDMI (WP5) M24 / 30-NOV-2025
- Validated shared decision-making (WP5) M24 / 30-NOV-2025
- OEI Requirement No. 3 (WP7) M24 / 30-NOV-2025

MILESTONES

- What has been recently submitted? Nothing
- What is upcoming?
- First patient inclusion in ETHER RCT (WP2) M13 / 31-DEC-2024 delayed to M16 / M31-MAR-2025
- First patient included in the Ethno-Morpheus Study (WP4) M7 / 30-JUNE-2024 delayed to M24 / 30-NOV-2025
- Completion of Delphi 2 (WP5) M22 / 30-SEP-2025 delayed to M25 / 31-DEC-2025
- Final functional TDMI integrated in a shared decision-making process (WP5) M22 / 30-SEP-2025 delayed to M25 / 31-DEC-2025
- Functional app for RCT (WP5) M24 / 30-NOV-2025 delayed to M27 / 28-FEB-2026
- First centre randomization in Ether RCT (WP2) M25 / 31-DEC-2025 delayed to M28 / 31-MAR-2026

Publications, Presentations at conferences and Communications

- What has been recently submitted or presented?
 - 06 June, Oral Communication, Gaëlle Munsch, Journée scientifique du GETBO, Brest, France
 - 06 June, Oral Communication, Francis Couturaud, Journée scientifique du GETBO, Brest, France

- 07 June, Oral Communication, Mauro Turrini, 4th Global Carework Summit: Histories and Futures of Care", Duke University, Durham, US
- 17 June, Oral Communication, Mauro Turrini, Workshop at the Department of Sociology and Business Law, University of Bologna, Italy
- 22 June, Oral Communication, Francis Couturaud, ISTH, Washington, US
- 05 July, ANTHROPO-MORPHEUS submitted for a first publication in Social Science & Medicine

What is upcoming?

- Manuscript on the Delphi1 results on Bleedings and recurrence of VTE with David Jimenez and WP5
- Manuscript on the whole project and on the ETHER study protocol.

Focus – Dissemination Rules

GOVERNED BY:

- The procedure of Article 17.4 of the Grant Agreement and its Annex 5, Section Dissemination,
- Article 9.4 Dissemination of the Consortium Agreement
- MORPHEUS Dissemination Plan

TO SUM UP:

- Disseminate results as soon as feasible in a publicly available format
- Each beneficiary disseminates its own results but transfer of results is possible
- All communication and dissemination activities <u>must acknowledge EU support and display the European flag and funding statement, with the following disclaimer</u> "Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or [name of the granting authority]. Neither the European Union nor the granting authority can be held responsible for them."



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Note that the deadlines noted in the CA are not the same, but that the GA deadlines prevail.

- Beforehand, each beneficiary must give at least 15 days advance notice to other beneficiaries, together with sufficient information in the results it will disseminate and any other beneficiaries may object within 15 days of receiving notification. An objection is justified if:
- The protection of the objecting Party's Results or Background would be adversely affected; or
- The objecting Party's legitimate interests in relation to the Results or Background would be significantly harmed, and/or
- The proposed publication includes Confidential Information of the objecting Party.
- Once the paper has been accepted for publication, deposit it in a trusted repository

AUTHORSHIP:

- The first publication of clinical trial results is under the responsibility of the sponsor and the study coordinating investigator will be listed as first author. All clinical investigators will be considered authors and will be listed in the published article as such, as well as the WP leads.
- Other publications of clinical trial results shall be submitted to the Sponsor for review prior submission and the study coordinating investigator will be listed as author.
- Outside the publications of clinical trial results:
 - Publication policy congress abstracts:
 - WP lead/Coordinator of the substudy determines the list of authors, including all those who contributed. Preferably the first authorship position is reserved for early career investigators.
 - The Coordinator is included as author and approves all abstracts before submission
 - Publication policy manuscripts:
 - WP lead/Coordinator of the substudy determines the list of authors, including all those who contributed. The first authorship position is reserved for early career investigators
 - The Coordinator is included as author, all WP leads are invited to be co-authors if they consider that they indeed fulfil the criteria of authorship
 - All manuscripts will be submitted 'on behalf of the Morpheus consortium'

Exceptions to these rules are possible but must remain exceptional. In all cases, they must be justified and validated by the coordinator and the consortium.