



Funded by the
European Union

“MORPHEUS” PROJECT

**PROGNOSIS IMPROVEMENT OF UNPROVOKED VENOUS THROMBOEMBOLISM
USING PERSONALIZED ANTICOAGULANT THERAPY**

HORIZON-HLTH-2022-TOOL-11-01

Tour d’Horizon

19 Septembre 2025



AGENDA

PROGNOSIS IMPROVEMENT OF UNPROVOKED VENOUS THROMBOEMBOLISM
USING PERSONALIZED ANTICOAGULANT THERAPY
HORIZON-HLTH-2022-TOOL-11-01

Le projet MORPHEUS et l'étude ETHER en quelques mots

Retour d'expérience sur l'étude clinique ETHER



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MORPHEUS

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The “MORPHEUS” project aims to reach 2 major objectives.

The first key objective : to **DEVELOP** a **time-dependent multicomponent intervention (TDMI) score integrated in a shared decision-making process** with the aim to optimize anticoagulation effectiveness.

Based on 2 approaches:

- 1- **Quantitative** : *literature, merged cohorts (“MC-MORPHEUS”)*
- 2- **Qualitative** : *socio-anthropology*

The second key and ultimate objective : to **VALIDATE** the effectiveness of the TDMI score integrated in a shared decision-making process.

- 1- **Quantitative** : *stepped wedge cluster randomized trial (“ETHER”)*
- 2- **Qualitative** : *ethnography*

MORPHEUS

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STRATOSPHERE



Call opening date: 06/10/2021

Full Stage:

Submission of the full proposal :
21/04/2022

Answer from the EU Commission:
05/08/2022 > **Reserve list**

Answer from the EU Commission:
05/06/2023 > **Approved**

≈6 Months

≈10 Months

≈5 Months

M0 = 1st DEC 2023



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M0 = 1st DEC 2023

1

M12 = 1st NOV 2024

2

M24 = 1st NOV 2025

3

M60 = 1st DEC 2028

Phase I: Preparation /
set-up of the program

Phase II: Derivation of
intervention phase

Phase III: Validation of intervention phase

Coordination WP1

Starting the studies

Discovery of new biomarkers and
validation

Literature review + "Delphi 1"

WP5
"Delphi 2"

Patients' interviews

Achievement of
TDMI integrated
a shared decision-
making process

Merged existing cohorts

Stepped wedge cluster RCT
until randomisation

WP2

Ethnographic study (patients and physicians)

WP4

Randomisations to intervention in stepped wedge
cluster RCT and achievement

WP2

Validation

Time-dependent multicomponent tool

PHYSICIAN

Outcomes
Predictors (precision
medicine)
Treatment options

PATIENTS

Outcomes
Predictors (patient's
centred medicine)
Treatment options

INTEGRATED IN SHARED MEDICAL DECISION

WP6

DISSEMINATION
to physicians and patients

WP5

ULTIMATE GOAL
MORPHEUS TOOL prevents
risk of recurrent VTE, bleeding and death

Regulatory process



Prognosis improvement of unprovoked v**E**nous **TH**romboEmbolism with the use of a shared decision-making process including a time-dependant multicomponent risk prediction scores int**ER**vention. An international academic two-stepped wedge cluster randomized trial.

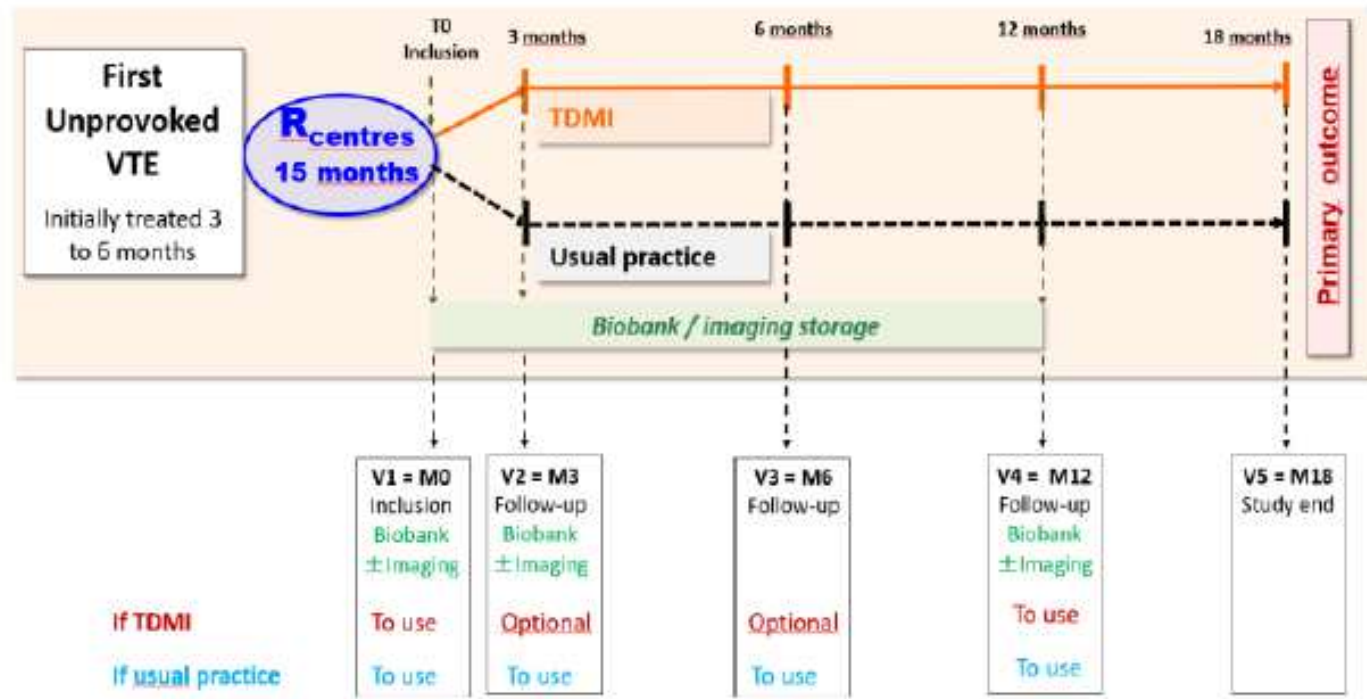


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Clinical study overview: ETHER

Full title: Prognosis improvement of unprovoked vEnous THromboEmbolism with the use of a shared decision-making process including a time-dependant multicomponent risk prediction scores intERvention. An international academic twosteped wedge cluster randomized trial.

Total number of patients: 2 400

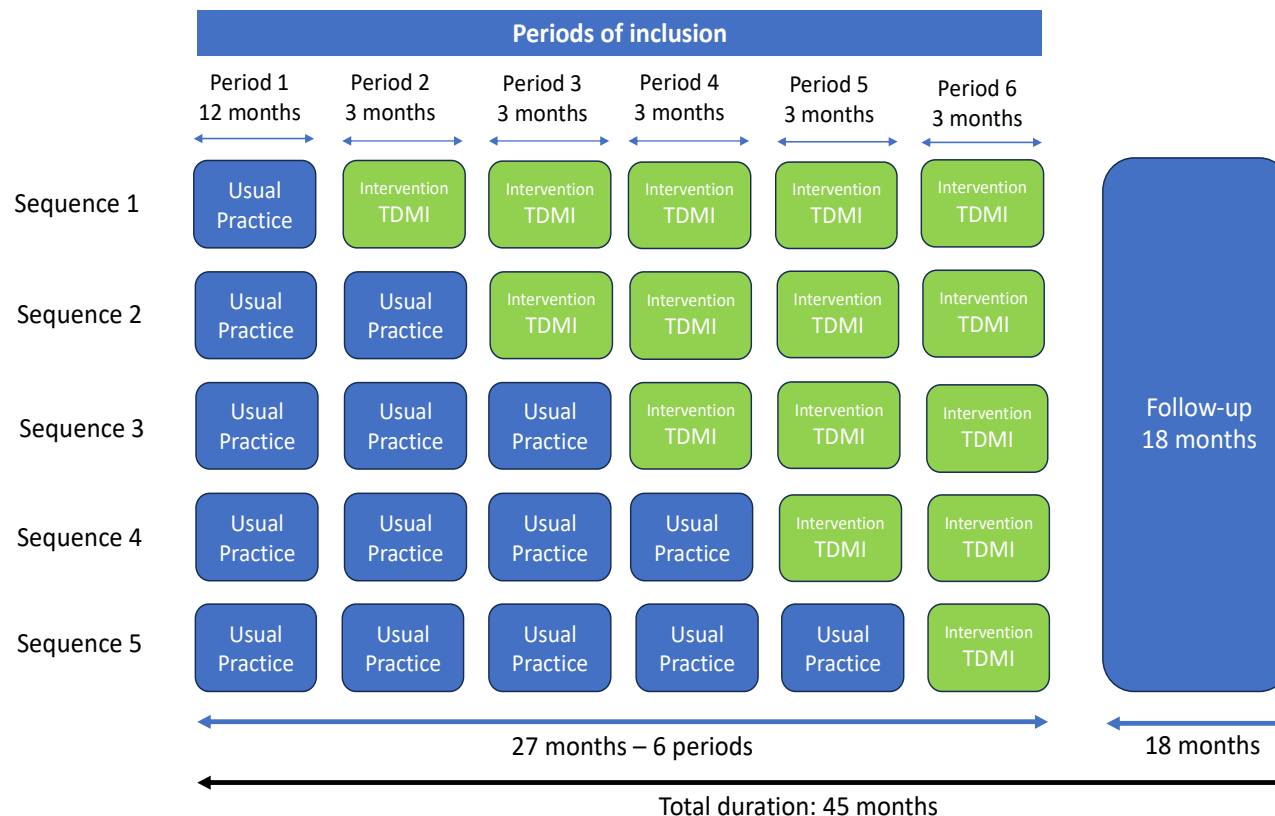


Clinical study overview: ETHER

Duration per patient: **18 months**

Duration of recruitment: **27 months**

Total ETHER duration: 45 months

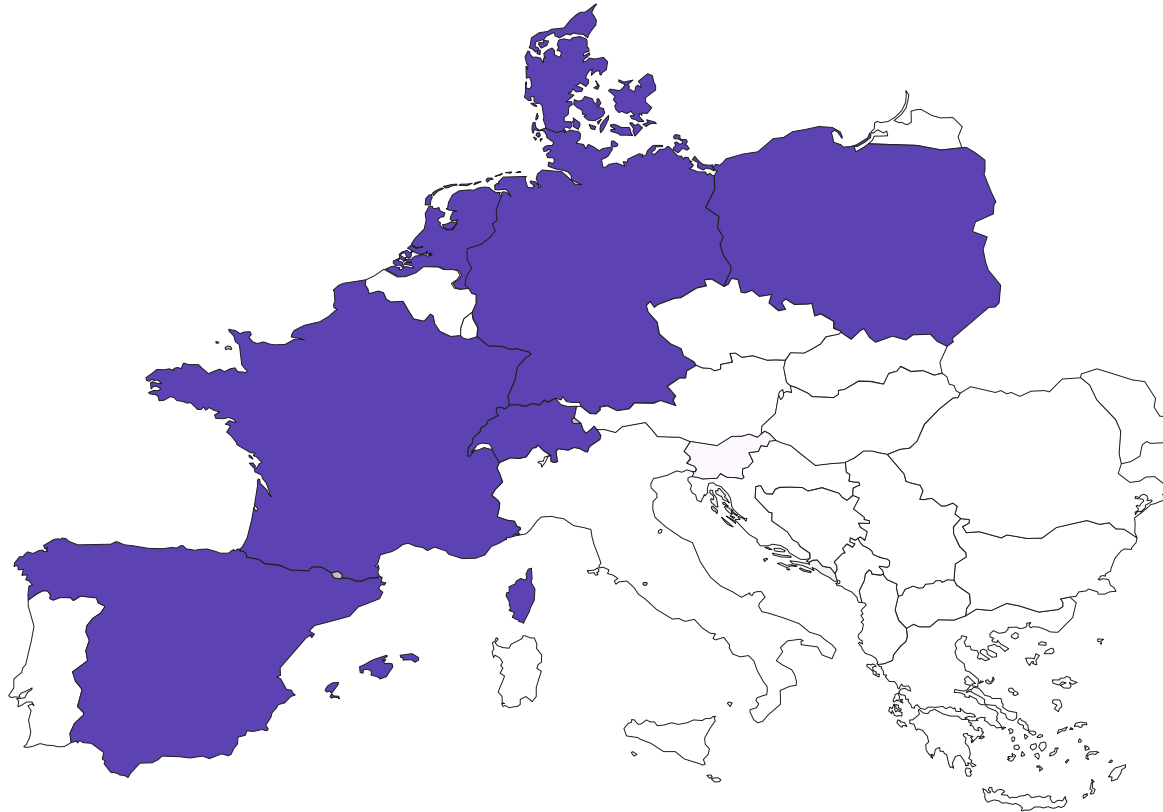


Clinical study overview: ETHER

Visit	V 1	V 2	V 3	V 4	V 5 / study end visit
Month	M0	M3	M6	M12	M18
Day	Day 0	90 ± 10	180 ± 30	365 ± 30	545 ± 30
Type of visit	Cs	Cs	Cs or Pc	Cs	Cs
Informed consent	X				
Inclusion/exclusion criteria	X				
Past medical history	X				
Concomitant treatments	X	X	X	X	
Questionnaires**	X	X			X
Biobank *	X	X*		X*	
Imaging collection ^{\$}	X	X	X	X	
TDMI application	X	X [£]	X [£]	X	
Treatment compliance***	X	X	X	X	X
Outcomes assessment		X	X	X	X
Adverse events		X	X	X	X

Clinical study overview: ETHER

■ Countries (sites): CHE (1), ESP (8), DEU (3), DNK (1), FRA (22), NLD (4) and POL (3).



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RETOUR D'EXPERIENCE ETHER

Autorisations
Questionnaires
Contractualisation RGPD
Consentement
Circuits
information
Vigilance
Centres Pays
Protocole
Budget
Procédures
logistiques
Qualification



RETOUR D'EXPERIENCE ETHER

Autorisations
Questionnaires
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Consentement
Circuits
information
Vigilance
Centres Pays
Protocole
Mep
Budget
Procédures
logistiques

- Protocole en anglais
- Qualification
- Circuits logistiques
(données, traitement, biocollection, Imagerie, etc ...)
- Pays et centres
- Lettre d'information/Consentement/Non opposition
(en français et en anglais)
- Soumission aux autorités compétentes dans chaque pays
- CRF
- Documents/**Questionnaires**/Procédures
- Contractualisation
- Mep
- RGPD



Dès la soumission du projet à l'AAP



BUDGET



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FACTEURS CLES DE SUCCES

Préparation
Coordonnateur
Expérience Réseau Réactivité
Temps **Budget** Moyens
Disponibilité ECSTN
Communication
Partenaires



FACTEURS CLES DE SUCCES

- Coordonnateur
- Budget
- Moyens
- Temps
- Expérience
- Réseau
- ECRIN
- Préparation
- Partenaires
- Communication
- Réactivité et Disponibilité



U1304



U1059

U1263

CIC 1412

CIC1408



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