STREAMLINED **GER**IATRIC AND **ON**COLOGICAL EVALUATION BASED ON IC **TE**CHNOLOGY
FOR HOLISTIC PATIENT-ORIENTED HEALTHCARE MANAGEMENT
FOR OLDER MULTIMORBID PATIENTS

HORIZON 2020 PROGRAMME – TOPIC H2020-SC1-BHC-24-2020
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Deliverable: 4.2 TRIAL COMMITTEES' CHARTERS

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GERONTE Consortium

Number	Participant Name	Short Name	Country
1	Université de Bordeaux	UBx	FR
	LTP1 : CHU Bordeaux	CHU Bx	
	LTP2 : Institut Bergonié	IB	
2	Katholieke Universiteit Leuven	KUL	BE
3	Stichting Diakonessenhuis	DIAK	NL
4	Oslo University Hospital	OUS	NO
5	University College Dublin	UCD	IE
6	E-Seniors	ESE	FR
7	MyPL SAS	MyPL	FR
8	Università Luigi Bocconi	BOC	IT
9	International Society of Geriatric Oncology	SIOG	CH
10	Dublin City University	DCU	IE

Disclaimer and acknowledgment

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Contributors

Contributor	Participant
Cecile Duchiron, GERONTE project manager	UBx – participant 1

Formal Reviewers

Contributor	Participant
Christine Schwimmer, EUCLID CTU Executive Director	UBx – participant 1

History of Changes

Version	Date	Author	Description of change
V1.0	2022-03-31	Cecile Duchiron [UBx]	First version
V2.0	2023-02-01	Lien Degol [KUL]	Modifications after input from European Commission

Table of Content

Executive Summary

Deliverable work status

Deliverable	Completion status in %	Deviation	Data complete or to be updated
D4.2 Trial committees' charters	100%	No deviations	Data complete
Associated Deliverables	/		
Associated Objectives	04 Demonstrate in 16 study sites from three EU countries the feasibility and effectiveness of the GerOnTe model		

Description of deliverable

The present document corresponds to the deliverable D4.2 "Trial committees' charters" of the GERONTE project, which has received funding from the European Union's Horizon 2020 Programme under Grant Agreement N° 945218. These charters will describe memberships, roles and responsibilities of the Trial Steering Committee (oversight body for the trials on behalf of the sponsor) and the Trial Management Team (set-up to carry out day-to-day management of the trials).

This deliverable is associated to O4 Demonstrate in 16 study sites from EU countries the feasibility and effectiveness in the GerOnTe model. A Trial Management Team (TMT) and Trial Steering Committee (TSC) will be established for coordination of the clinical trials FRONE and TWOBE. These clinical trials will be performed with the aim of providing a proof of concept of the GerOnTe model in three European countries, France, Belgium and the Netherlands.

Attainment of the objectives and explanation of deviations

The objectives related to this deliverable have been achieved in full and as described in Annexe 1 (Description of the Action Part A) of the Grant Agreement N°945218.

Justification for delay in deliverable submission

The objectives related to this deliverable have been achieved on time and as scheduled in Annexe 1 (Description of the Action Part A) of the Grant Agreement N°945218.

Glossary

CTU	Clinical Trials Unit
TMT	Trial Management Team
TSC	Trial Steering Committee

1. Introduction

1.1. GERONTE and its objectives

GERONTE is a 5-year research and innovation project (April 2021 to Mars 2026) funded by the European Union within the framework of the H2020 Research and Innovation programme, in response to the health societal challenge topic SC1-BHC-24-2020 "Healthcare interventions for the management of the elderly multimorbid patient". The overall aim of GERONTE is to improve quality of life - defined as well-being on three levels: global health status, physical functioning and social functioning- for older multimorbid patients, while reducing overall costs of care. To this end, GERONTE will co-design, test, and prepare for deployment an innovative cost-effective patient-centred holistic health management system, hereafter referred to as the GERONTE intervention. GERONTE intervention will rely on an ICT based application (Holis^{TM}) for real-time collection and integration of standardised clinical and home patient-reported data. GERONTE intervention will be demonstrated in the context of care of multimorbid patients having cancer as a dominant morbidity, and be adaptable to any other combination of morbidities.

Objectives

O1: INFORMATION gather the stakeholders and data needed for patient-centred and multi-actor complex decision-making process and management

O2: **TOOLS** develop ICT tools for the GERONTE intervention to be implemented

O3: METHODS develop socio-economic methods for evaluating the impacts of the implementation of the GERONTE intervention

O4: **DEMONSTRATION** demonstrate in 16 study sites from three EU countries the feasibility and effectiveness of the GERONTE intervention

O5: **REPLICATION** develop recommendations for the replication of GERONTE best practices in all European health systems

O6: ENGAGEMENT engage all stakeholders by co-designing the GERONTE intervention

1.2. Rationale

The current work corresponds to deliverable D4.2, which is part of work-package 4, which supports GERONTE objective 3 "Demonstration and validation". The objective of WP4 is to perform two clinical trials, i.e. FRONE in France and TWOBE in Belgium and the Netherlands, in accordance with ethical and regulatory requirements. The goal is to provide a Proof of Concept of the GerOnTe model in three distinct European countries, and (i) to provide data on how the GerOnTe intervention fits into different health organisation systems, and (ii) to quantify the effectiveness and efficiency of GerOnTe system.

2. Trial Steering Committee (TSC) charter

The purpose of the TSC charter is to describe the membership, terms of reference, roles, responsibilities, authority, decision-making and relationships of the TSC for GERONTE trials, including the timing, frequency and format of meetings, methods of providing information to and from the TSC and relationships with other trial committees.

The TSC Charter is detailed in Appendix 1.

3. Trial Management Team (TMT) charter

The Trial Management Team (TMT) is the operational team that undertakes the day-to-day management of the GERONTE trials.

The TMT Charter is detailed in Appendix 2.

APPENDIX 1: Trial Steering Committee (TSC) charter

Trial Steering Committee (TSC) charter

Version 0.1 du 29/03/2022

GERONTE consortium FRONE and TWOBE Trials

Sponsors: Institut Bergonié (FRONE) and Katholieke Universiteit Leuven (TWOBE)

Coordinating Investigators: Pierre Soubeyran and Hans Wildiers

NCT: TBD at submission

STREAMLINED GERIATRIC AND ONCOLOGICAL EVALUATION BASED ON IC TECHNOLOGY FOR HOLISTIC PATIENT-ORIENTED HEALTHCARE MANAGEMENT FOR OLDER MULTIMORBID PATIENTS

Clinical Trials Unit (CTU): EUCLID

Writing / Update	EUCLID CTU Project manager Dr Cécile Duchiron	***Signature***
Validation	EUCLID CTU representative Dr Christine Schwimmer Sponsor representative Pr Simone Mathoulin-Pelissier	***Signature*** ***Signature***
Approbation	Coordinating investigator FRONE trial: Pr Pierre Soubeyran TWOBE trial: Pr Hans Wildiers	***Signature***
Dissemination	TSC members	

CONTENT OF THE CHARTER

Charter	
1. Introduction	
Outline of scope of Charter	The purpose of this document is to describe the membership, terms of reference, roles, responsibilities, authority, decision-making and relationships of the TSC for GERONTE trials, including the timing, frequency and format of meetings, methods of providing information to and from the TSC and relationships with other trial committees.
Facilitation	A member of the Clinical Trials Unit (CTU). EUCLID (Project Manager) has been nominated as a TSC Facilitator for the trials. The TSC Facilitator will be responsible for the organisation of meetings and should be copied into all communications with and between the TSC.
2. Roles and responsibilities	
A broad statement of the aims of the TSC	The Trial Steering Committee (TSC) is the group that provides overall supervision for the trials on behalf of the sponsors.
Specific roles of the TSC	• provide expert oversight of the trials • maintain confidentiality of all trial information that is not already in the public domain • make decisions as to the future continuation (or otherwise) of the trials • receive and react to recruitment rates and encourage the Trial Management Team (TMT) to develop strategies to deal with any recruitment problems • approve the trial protocols • review regular reports of the trials progress from the TMT • oversee that the trials conduct is compliant with ethical principles of clinical research and respects participants' interest • assess the impact and relevance of any accumulating external evidence • monitor follow-up rates and review strategies of the TMT to deal with major problems • censure sites that are deviating from the protocol • approve any amendments to the protocol, where appropriate • approve any proposals by the TMT concerning any change to the design of the trial, including additional sub-studies • oversee the timely reporting of trial results, including to investigators and participants • approve / comment on the statistical analysis plan • approve / comment on the publication policy • approve / comment on the main trial manuscript

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	• approve / comment on any abstracts and presentations of any results *during and after* the running of the trials • approve/comment any external communication on the trials, including press release to the lay public • approve external or early internal requests for release of data or subsets of data including clinical data.
3. Before or early in the trial	
Whether members of the TSC will have a contract	TSC members will not be asked to formally sign a contract but should formally register their agreement to join the group by confirming (1) that they agree to be a member of the TSC and (2) that they agree with the contents of this Charter. Any potential competing interests should be declared at the same time. Members should complete and return the form in Appendix 2. Any observers (attendees who are not members) will sign a confidentiality agreement on the first occasion they attend a meeting (Appendix 2).
4. Composition	
Membership of the TSC	The membership will be made up of voting and non-voting members, permanent invited observers and invited observers (Appendix 1). The charter will be amended for each modification of the membership. New agreement corresponding to the new version of the charter will be signed only for modification concerning voting-members.
Tenure	TSC members are nominated for the entire duration of the study. However, if for any reason they need to end their participation, they will be replaced.
The responsibilities of the Facilitator	The TSC Facilitator will be responsible for arranging meetings of the TSC, coordinating reports, producing and circulating minutes and action points. The Facilitator will be the central point for all TSC communications between the TSC and other trial bodies, will be copied into all correspondence between TSC members, and will be kept aware of trial issues as they arise.
The responsibilities of the observers	Observers may be in attendance through the TSC meetings in order to provide input on behalf of the Trial Management Team, the sites, the trial's Sponsors or to provide specific relevant expertise. Ad hoc observers may be invited as needed.

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5. Relationships	
Relationships with Coordinating investigators, other trial committee (TMT), Sponsors and regulatory bodies	The responsibilities of each trial committee are detailed in the protocol and in the respective Charters.
The need for TSC members to disclose information about any real or potential competing interests	Any competing interests, both real and/or potential, should be disclosed. These are not restricted to financial matters – involvement in other trials or intellectual investment could be relevant. Although members may well be able to act objectively despite such connections, complete disclosure enhances credibility. (See Appendix 2)
6. Organisation of meetings	
Expected frequency of TSC meetings	The TSC will meet at least yearly face-to-face or via conference calls every 6 months. At the request of the TSC or sponsors, interim meetings, in person or by teleconference, can be organised at any time. Major trials issues may need to be dealt with between meetings, by phone or by email. TSC members should be prepared for such instances.
Attendance of TSC members at meetings	Effort will be made for all members to attend. The TSC Facilitator will try and identify a date that enables this. For Face-to-Face meetings, attendance will be recorded by participant signatures on the attendance list prepared by the TSC Facilitator. Otherwise, attendance will be recorded in the TSC report. If the TSC is considering a major action, the TSC Chair, assisted by the TSC Facilitator, should communicate any decision to the absent members as soon as possible after the meeting. If they do not agree with the decision made, a teleconference should be arranged with the full TSC. Generally, the TSC should be able to reach a decision by consensus. However, rarely, if there is strong disagreement amongst the TSC members, then this should be resolved by means of a vote. All TSC members should participate in the TSC discussions but only voting members should cast a vote.
How TSC meetings will be organised, especially regarding open and closed sessions, including who will be present in each session	Presence will be usually limited to the TSC members, permanent observers, and the TSC Facilitator. Other attendees may be invited for all or part of the meeting by the TSC. The observers are not members of the TSC but may be invited to provide expert input; other observers

Charter	
	will be at the discretion of the TSC and the TSC Facilitator but may include other members of the TMT.
Content of meetings	A draft agenda for the meeting will be developed by the TSC Facilitator and should include a review of the TMT reports and any particular issues needing to be discussed at the meeting. The agenda has to be approved by the TSC chair prior to the meeting and is to be distributed to TSC members with the report.
7. Decision making	
What decisions will be open to the TSC	Possible decisions include: • No action needed, trial continues as planned • Early stopping • Stopping recruitment within a subgroup. Modifying target recruitment. • Stopping one or more arms • Sanctioning and/or proposing protocol changes • Censuring centres for poor recruitment/poor data quality • Approving proposed protocol amendments or new trial sub-studies • Approving requests for early release of (subsets of) data. • Approving presentation of results during the trial or soon after closure • Approval of new strategies to improve recruitment or follow-up
How decisions or recommendations will be reached within the TSC	Every effort should be made to achieve consensus. The role of the Chair is to summarise discussions and encourage consensus; therefore, it is usually best for the Chair to give their own opinion last. It is important that the implications (e.g. ethical, statistical, practical, financial) for the trials be considered before any decision is made.
8. Reporting	
To whom will the TSC report their recommendations/decisions, and in what form	The TSC will report their decisions (via the TSC Facilitator) to the TMT. The TMT will be responsible for implementing any actions resulting from the TSC meeting. The TSC may also provide feedback, where appropriate, to the Sponsors. Copies of communications will pass through the TSC Facilitator.
Whether minutes of the meeting be made and, if so, by whom and where they will be kept	The TSC Facilitator will keep a central record of all minutes, reports and correspondence by the TSC.

9. After the trial

Publication of results	The TSC will oversee the timely analysis, writing up and publication of the main trials results.
The information about the TSC that will be included in published trial reports	TSC members will be named and their affiliations listed in the main report, unless they explicitly request otherwise. This will be done in compliance with GERONTE trials publication policy, which is approved by the TSC.

10. Definitions and abbreviations

GERONTE	Streamlined geriatric and oncological evaluation based on IC technology for holistic patient-oriented healthcare management for older multimorbid patients
TMT	Trial Management Team
TSC	Trial Steering Committee

11. Appendices

Appendix 1 – Composition of the Trial Steering Committee

Appendix 2 – Agreement and competing interests form for TSC members

Appendix 3 – Agreement and competing interests form for observers

APPENDIX 1 – Composition of the Trial Steering Committee

Role	Name	Institution
Voting Members		
Coordinating investigator FRONE, and consortium chair - Chair	Pierre Soubeyran	Institut Bergonié, FRANCE
Coordinating investigator TWOBE, Co-chair	Hans Wildiers	Katholieke Universiteit Leuven, BELGIUM
Principal investigator NL, geriatric expert	Marije Hamaker	Stichting Diakonessenhuis, Utrecht, NETHERLANDS
Geriatrician independent member	Suzanne Festen	University Medical Centre Groningen, Groningen, NETHERLANDS
Methodologist independent member	Florence Canoui-Poitrine	AP-HP Hôpital Henri Mondor, Paris, FRANCE
Oncologist , independent member	Nicolo Battisti	The Royal Marsden Hospital, London, UNITED KINGDOM
Sponsor representative - Head of "Sponsor Department"	Simone Mathoulin Pelissier	Institut Bergonié, FRANCE
Sponsor representative	*Pending*	Katholieke Universiteit Leuven, BELGIUM
Trials Methodologist	Florence Saillour-Glenisson	EUCLID, Bordeaux, FRANCE University of Bordeaux, FRANCE University Hospital of Bordeaux, FRANCE
EUCLID CTU representative	Christine Schwimmer	EUCLID, Bordeaux, FRANCE University of Bordeaux, FRANCE University Hospital of Bordeaux, FRANCE
Non-voting Members		
Sub-study leader ""	Lucia Ferrara	Universita Commerciale Luigi Bocconi, Milano, ITALY
Sub-study leader ""	Anthony Staines	University College Dublin, University of Ireland, Dublin, IRELAND
Trials Statistician	Marion Kret	EUCLID, Bordeaux, FRANCE University of Bordeaux, FRANCE University Hospital of Bordeaux, FRANCE
Patients representative	*Pending*	
MyPL representative	*Pending*	
TSC Facilitator, EUCLID project manager	Cécile Duchiron	EUCLID, Bordeaux, FRANCE University of Bordeaux, FRANCE Institut Bergonié, FRANCE
Permanent invited observers		
EUCLID senior Project Manager	Caroline Lalet	EUCLID, Bordeaux, FRANCE Institut Bergonié, FRANCE
EUCLID junior Methodologist	Julie Arsandaux	EUCLID, Bordeaux, FRANCE University of Bordeaux, FRANCE

EUCLID representative	Cédrick WALLET	EUCLID, Bordeaux, FRANCE University of Bordeaux, FRANCE University Hospital of Bordeaux, FRANCE
KUL representative	Lien Degol	Katholieke Universiteit Leuven, BELGIUM
GERONTE Project Manager	*Pending*	University of Bordeaux, FRANCE
Invited observers ad hoc		
Ad hoc observers may be invited as needed, e.g. to provide specific expertise or discuss specific matters.		

Appendix 2: Agreement and competing interests form for TSC members

Streamlined geriatric and oncological evaluation based on IC technology for holistic patient-oriented healthcare management for older multimorbid patients (GERONTE)
Trial Steering Committee: Agreement to join the Trial Steering Committee as a member and disclosure of potential competing interests.

Please complete the following document and return original to the TSC Facilitator.
(please initial box to agree)

	I have read and understood the TSC Charter version xx.x, dated __/___/____
	I agree to join the Trial Steering Committee for this trial as a member
	I agree to treat all sensitive trial data and discussions confidentially

The avoidance of any perception that a member of a TSC may be biased in some fashion is important for the credibility of the decisions made by the TSC and for the integrity of the trials.

Potential competing interests should be disclosed via the TSC facilitator. In many cases simple disclosure up front should be sufficient.

☐ **No,** I have no potential competing interests to declare
☐ **Yes,** I have potential competing interests to declare (please detail below)

Please provide details of any potential competing interests:

_____
_____
_____

Name: _____

Signed: _____ Date: _____

Appendix 3: Agreement and competing interests form for observers

Streamlined geriatric and oncological evaluation based on IC technology for holistic patient-oriented healthcare management for older multimorbid patients (GERONTE)
Trial Steering Committee: Agreement to join the Trial Steering Committee as a member and disclosure of potential competing interests.

Please complete the following document and return original to the TSC Facilitator.

(please initial box to agree)

☐	I have received a copy of the TSC Charter version xx.x, dated __/___/____
☐	I agree to treat as confidential any sensitive information gained during this meeting unless explicitly permitted

Potential competing interests should be disclosed via the TSC facilitator. In many cases simple disclosure up front should be sufficient.

☐ **No,** I have no potential competing interests to declare
☐ **Yes,** I have potential competing interests to declare (please detail below)

Please provide details of any potential competing interests:

_____

_____

_____

Name: _____

Signed: _____ Date: _____

APPENDIX 2: Trial Management Team (TMT) charter

Trial Management Team (TMT) charter

Version 0.1 du 29/03/2022

GERONTE consortium FRONE and TWOBE Trials

Sponsors: Institut Bergonié (FRONE) and Katholieke Universiteit Leuven (TWOBE)

Coordinating Investigators: Pr Pierre Soubeyran (FRONE) and Pr Hans Wildiers (TWOBE)

NCT: TBD at submission

STREAMLINED GERIATRIC AND ONCOLOGICAL EVALUATION BASED ON IC TECHNOLOGY FOR HOLISTIC PATIENT-ORIENTED HEALTHCARE MANAGEMENT FOR OLDER MULTIMORBID PATIENTS

Clinical Trials Unit (CTU): EUCLID

Writing / revision	EUCLID CTU Project manager Dr Cécile Duchiron	***Date et Signature***
Validation	EUCLID CTU representative Dr Christine Schwimmer Sponsor representative Pr Simone Mathoulin-Pelissier	***Date et Signature*** ***Date et Signature***
Approbation	Coordinating investigators FRONE trial: Pr Pierre Soubeyran TWOBE trial: Pr Hans Wildiers	***Date et Signature***
Diffusion	TMT members	

CONTENT OF THE CHARTER

1. Role

The Trial Management Team (TMT) is the operational team that undertakes the day-to-day management of the GERONTE consortium's FRONE and TWOBE trials.

2. Members

The TMT consists of the following members: coordinating investigators, sponsor representatives, national coordinating team representatives, and sub-study representatives, CTU representatives, EUCLID trial study team, safety officer (where appropriate).

The nominative list of the TMT members is detailed in Appendix 1 and kept updated by EUCLID.

3. Functioning

The TMT meets either by tele/visioconferences or Face-To-Face. Additional participants may be invited as appropriate. Meetings are organised by EUCLID.

Regular meetings

Regular meetings are usually held at monthly intervals although may be needed more frequently in the critical phases of the trial, and less frequently when enrolment is closed and there are no specific issues arising. Effort will be made to gather most if not all members at each meeting. Maintaining a regular meeting pattern takes precedence over the presence of all members, i.e. meetings should not be postponed or cancelled for > 2 months, except in exceptional circumstances. Announcing the schedule of meetings several weeks or months in advance and advertising the next meetings at each meeting is the mean used to help all members booking their own agenda for this specific meeting.

The primary objective of regular meetings is to share concise reporting of all activities. Reporting may include updates on regulatory status per country, updates on study documents, distribution of inclusions per site, recruitment difficulties, participants with discontinuation of follow-up, monitoring visits, safety matters if applicable, and any other relevant trial management activities. In each phase of the trial, the agenda follows a predefined scheme whenever possible.

Each member/entity is responsible for the preparation of documents and reporting regarding the activities he or she coordinates. All relevant documents for the meeting are made available to the

participants at least 2 days before the meeting. Each contributor uses a standardised report form (Trial Management Report) to report on the progress of the trial regarding their activities.

Extraordinary meetings
Extraordinary (ad-hoc) meetings may be convened in case of urgent matters. In this case the agenda of the meeting is to be adapted to the circumstances.

Document exchange
Minutes from TMT meetings or TMT reports are recorded by EUCLID, circulated to the TMT group and approved at the beginning of the next meeting.

4. Accountability

The TMT is accountable to the Trial Steering Committee, and to the Trial sponsors for specific matters such as budget.
Minutes or TMT reports are made available to sponsors and TSC members.

5. Decision making

Whenever possible, decision is reached by a consensus of the TMT members. When this is not possible, the final decision lies with the Trial Steering Committee for missions defined in the TSC charter, and with the trial sponsor for specific matters, such as budget.

6. Interaction with other Trial Committees

The TMT (represented by the TMT chair) formally reports to the Trial Steering Committee (TSC) on the progress of the trial periodically. This takes place at the regular meetings of the TSC, but any interim urgent issues will be communicated to the Chairman of the TSC as they arise, and the Chairman ensures appropriate communication to the TSC with ad-hoc meetings organised if needed.

APPENDIX 1 – Trial Management Team

Chair of the TMT: Hans Wildiers

Co-Chair: Pierre Soubeyran

- **Members**

	Members
Coordinating investigator TWOBE, PI Belgium	Hans Wildiers
Coordinating investigator FRONE, PI France	Pierre Soubeyran
Principal Investigator TWOBE The Netherlands, geriatric expert	Marije Hamaker
Sponsor representatives	Simone Mathoulin-Pelissier *KUL representative pending*
Substudy leaders	Lucia Ferrara
	Anthony Staines
EUCLID CTU Executive Director	Christine Schwimmer
EUCLID CTU Operations Manager	Cédrick Wallet
Methodologist	Florence Saillour-Glenisson
Junior Methodologists	Julie Arsandaux Florence Francis
Senior project Manager	Caroline Lalet
Project Manager (facilitator)	Cécile Duchiron
KUL representative, BE and NL sites coordinator	Lien Degol
KUL site Advance Practice Nurse	Cindy Kenis
Coordinating Clinical Research Associate	TBD
Statistician	Marion Kret
Data manager	TBD
GERONTE project manager	*Pending*

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