



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

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**D4.14 – End of study activities for TWOBE**

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## History of Changes

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## GERONTE Consortium

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3	Stichting Diaconessenhuis	DIAK	NL
4	Oslo University Hospital	OUS	NO
5	University College Dublin	UCD	IE
6	E-Seniors	ESE	FR
8	Università Luigi Bocconi	BOC	IT
9	International Society of Geriatric Oncology	SIOG	CH
10	Dublin City University	DCU	IE
11	myPatientSpace	MPS	IE



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## D4.14 – End of study activities for TWOBE

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## 2. Introduction

### 2.1. Geronte and its objectives

At the beginning of the GerOnTe project, the plan was to carry out two trials in two different European geographical areas (France (FRONE) and Belgium-Netherlands (TWOBE)) in order to take into account the role of health care contexts in the implementation, effectiveness and efficiency of the GerOnTe system. These geographical areas were chosen based on :

- (i) feasibility (presence of experienced partners and capacity of investigating centres to include enough participants),
- (ii) maturity of primary care organisations
- (iii) And costs.

As previously shown by the European PHAMEU project, primary care varies widely in Europe with strong, medium and weak organisations. We hypothesised that weak countries will not be able to implement the GerOnTe care pathway in the course of the project. Belgium and the Netherlands have in common a strong maturity while France outlines a medium strength of primary care organisations. Similarly, geriatric oncology practice varies widely among European countries, France and Belgium being in a better situation thanks to successive Cancer Plans. This is the reason why we chose these three countries, which have the capacity to conduct large trials in geriatric oncology (with the experience of partners KUL and UBx) with all the necessary network elements guaranteeing the capacity to conduct the trial. Beside choice of geographical areas, implementation of our digital solution in eHR will take time and resources, limiting the number of investigating centres to 16 overall, eight per trial.

Throughout the project, various challenges in Belgium and the Netherlands - such as difficulties with submissions to Competent Authorities under the Medical Device Regulation (MDR), contractual agreements, collaboration issues with MyPL, and the need for innovative evaluation methods for programs targeting multimorbid patients - led to modifications in the project methodology, resulting in the adoption of hybrid evaluation methods. We had reached a stage where this was no longer feasible to conduct TWOBE within the timeframe of the project. Indeed, the bankruptcy of Mypl on the 30<sup>th</sup> of January 2024 led to relaunch the full regulatory process from the beginning according to Belgian law which made it impossible to complete in the current H2020 timeframe. We therefore decided to perform the trial (FRONE) in France and conduct an observational cross-sectional study (IMPLEMENT Study) across five European countries which is overall beneficial to the project. Indeed, it will analyse the country contexts of multimorbid patients management and will finally improve our level of preparation for further implementation of the GERONTE pathway. France investigating centers in FRONE were chosen based on feasibility, the strength of primary care organisation and cost, while the Countries involved in the IMPLEMENT Study (France, Belgium, Netherlands, Italy, Ireland) were selected to account for the high heterogeneity of healthcare systems.

### 2.2. Deliverable

This deliverable provides an overview of the actions taken to officially close TWOBE. All approvals are email replies (mostly in Dutch), which can be shared if necessary.

### 3. Competent authorities

#### 3.1. Belgium

- Federal Agency for medicines and health products (FAMHP):
  - Submission 'notification of early termination' on August 7 2024
  - Reminder submission 'notification of early termination' on October 1 2024
  - Approval of 'notification of early termination' on October 1 2024 (see e-mail FAMHP)

#### 3.2. the Netherlands

- Medical Research Ethics Committees United (MEC-U):
  - Submission 'notification of early termination' on August 7 2024
  - Approval of 'notification of early termination' on August 15 2024 (see e-mail MEC-U)

### 4. Individual sites

#### 4.1. Belgium

- UZ Leuven, Leuven:
  - Submission 'notification of early termination' on September 5 2024
  - Reminder submission 'notification of early termination' on October 1 2024
  - Approval of 'notification of early termination' on October 1 2024
  
- AZ Sint Jan, Brugge:
  - Submission 'notification of early termination' on August 8 2024
  - Approval of 'notification of early termination' on August 22 2024
  
- AZ Groeninge, Kortrijk:
  - Submission 'notification of early termination' on August 8 2024
  - Reminder submission 'notification of early termination' on October 1 2024
  - Approval of 'notification of early termination' on October 1 2024 of Clinical Trial Center
  - Approval of 'notification of early termination' on October ... 2024 of Ethics Committee

- UZ Brussel, Brussel:
  - Submission 'notification of early termination' on August 8 2024
  - Reminder submission 'notification of early termination' on October 1 2024
  - Approval of 'notification of early termination' on October 1 2024

## 4.2. the Netherlands

- Diaconessenhuis, Utrecht:
  - Request for submission of notification of MEC-U closure on August 28 2024
  - Confirmation of internal closure on August 28 2024 (see e-mail Susanne Leij-Halfwerk)
  
- Catharina ziekenhuis, Eindhoven
  - Request for submission of notification of MEC-U closure on August 28 2024
  - Reminder of request for submission of notification of MEC-U closure on October 1 2024
  - Reminder of request for submission of notification of MEC-U closure on March 3 2025
  - Confirmation of internal cancellation on March 3 2025 (see e-mail Wetenschapsbureau)
  
- Maasstad ziekenhuis, Rotterdam
  - Request for submission of notification of MEC-U closure on August 28 2024
  - Reminder of request for submission of notification of MEC-U closure on October 1 2024
  - Reminder of request for submission of notification of MEC-U closure on March 3 2025
  - Reminder of request for submission of notification of MEC-U closure on March 11 2025
  - Confirmation of internal closure on March 13 2025 (see e-mail Juliette van den Berg)

- Leiden University Medical Center, Leiden
  - Request for submission of notification of MEC-U closure on August 28 2024
  - Confirmation of internal closure on August 28 2024 (see e-mail Frederiek van den Bos)

## 5. Internal procedures KU Leuven

- 'Interne aankoopdienst':
  - Confirmation of closing all 6 internal procedures (Q21-1952 - Q21-1957) at KU Leuven on August 19 2024 (see e-mail Evelien Audenaert)

## 6. Clinicaltrials.gov

- GERONTE TWOBE: 'withdrawn' – date 08/08/2024
  - NCT05423808
  - Confirmation of approval 'withdrawn' on August 12 2024.



[www.geronteproject.eu](http://www.geronteproject.eu)



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