

# NEWSLETTER

A STAKEHOLDER COMMUNICATION FROM THE GERONTE CONSORTIUM SEPTEMBER 2023, ISSUE 2

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement 945218.



















Università Commerciale Luigi Bocconi







# MESSAGE FROM THE SCIENTIFIC COORDINATOR

Development of clinical research in geriatric oncology has always been difficult since, up to now, sponsors, authorities and even colleagues have never considered it as a priority. The GERONTE program is the cornerstone of a sharp evolution since we have raised a very competitive grant through the European framework programme H2020. This shows that our fight is now acknowledged at the top.

Yet, challenges to working simultaneously on the organisation of care and digital medicine remain. In the last two years, we have faced issues with GDPR, changes to European regulations on digital health research, and digital data sovereignty, as Europe has some of the highest health data and GDPR standards. These challenges have been difficult for the consortium, especially our technical partner MyPL, as we have had to adapt at each step. Although these changes will no doubt benefit individual rights, they impact research development by adding to the complexity of the preparation of project implementations.

Nonetheless, we have made it. The FRONE and TWOBE trials have successfully gone through the necessary regulatory processes of each country's competent authorities. Although we still have a few steps ahead of us, we are close to the end of this preliminary part of the programme.

Indeed, our trials are already complex to implement in investigating centres since they will change daily routines and only for a limited proportion of patients. This requires tremendous efforts from each of the investigating centres, and we would like to thank the community hospitals which accepted to take on the challenge of these trials with us.

Not to mention that all 16 centres will also take part in the ancillary studies of WP3 led by Lucia Ferrara for health economics and of WP5 led by Anthony Staines for the realist evaluation. We purposefully chose these hospitals for the best to ensure the representativity of the elderly population, and we will have to support them.

During these last months, clinical trial teams have made tremendous efforts to make it work. Above all, Eléonore Lehn did a marvellous job keeping everything on track, which was always tough. We have also to acknowledge our lead project managers, Aurore Barthod-Malat and, from now on, Célia Fourrier, our central clinical research assistant Kinkle Vodjogbe, and also the research team of Institut Bergonié with their staff Géraldine Robert, Lucie Creno, Sophie Lassé, Sandrine Barbotin and Caroline Lalet, but also, of course, the heads of both the research department and the institute itself, whose support has been crucial. On the TWOBE side, Lien Degol and Cindy Kenis did a tremendous job. Thank you also to the highly competent EUCLID team with Christine Schwimmer, Cedrick Wallet and, more recently, Vincent Thévenet as well as the research and GDPR departments of the University of Bordeaux.

Thanks to the multiple competencies of our consortium, we have kept going and will be able to launch the two clinical trials, FRONE in France and TWOBE in Belgium and the Netherlands by the end of the year. This will be the occasion for the 16 centres of these three countries to experience a patient-centred management where patients' medical data, including cancer and concomitant morbidities and geriatric assessment as well as patient's expectations and priorities will be considered for decision-making during the multidisciplinary tumour boards.

Finally, the Mypl development team, led by Eduardo Bonnefemne as Lead Product Manager, is very close to completing the final technical issues and training tools for the HolisTMGV apps in order to be ready for site initiation visits. And we should thank Christophe Vergne and Jean-Alexandre Kaminisky for their continuous dedication to the programme. They built the app according to the results of WP1, led by Marije Hamaker with Nelleke Seghers as an outstanding driver. Implementing these apps in the 16 investigating centres will be a key process for the success of GERONTE.

**Prof. Pierre Soubeyran, MD** Professor of Medical Oncology University of Bordeaux, France

# LATEST NEWS EVENTS IN 2023

# Bocconi's Abstract was Accepted!

GERONTE will be present at the EUPHA conference in Dublin with a poster that analyses the existing care pathway in the 16 clinical sites involved in the project. This conference provides a valuable platform to highlight initial findings regarding the factors that can influence the provision of high-quality care for patients with multiple chronic conditions.

## Care pathways for older multimorbid patients: lessons learned from 16 clinical sites in 3 countries

Authors: Lucia Ferrara, Vittoria Ardito, Valeria D. Tozzi,

Bridget O'Sullivan, Anthony Staines, Paul Davies, Rosanna Tarricone.

### **Background:**

The fact that multimorbid and vulnerable patients need improved care coordination is well known. However, the current healthcare system is still mainly single-disease oriented and as a result, coexisting morbidities often need to be more evaluated and under-managed, leading to inappropriate care, inefficiencies, duplication and poor quality of care. We also know that different strategies have been developed to manage older multimorbid patients and varies from one country to the other. Therefore, we aimed to describe the care pathway for older, multimorbid cancer patients to understand current practices and shed light on the care pathways currently followed by the 16 clinical sites in three countries participating in an EU-funded research project.

### **Results:**

The analyses highlighted high variability in the process of care of older multimorbid patients across countries and centres. In particular, the organisational context in which each site is embedded affects its operating conditions, and there are at least three dimensions that affect the delivery of patient care: a) the scope of the services offered by each clinical site within the care pathway; b) the relationships between health care professionals, including access to specialist knowledge; c) the tools available to ensure integration between the different professionals in the different stages of the care pathway.

# Congratulating Hans Wildiers

GERONTE applauds Hans Wildiers for receiving the ASCO 2023 Special Award: B.J. Kennedy Geriatric Oncology Award. Hans Wildiers, MD, PhD, medical oncologist at the University Hospital Leuven in Belgium has been honored with the 2023 B.J. Kennedy Geriatric Oncology Award for his career-long contributions to advancing clinical research in breast cancer in older populations. Dr. Wildiers presented a lecture in recognition of the award mentioning the GERONTE Project during the 2023 ASCO Annual Meeting.



### Work Package 3 Work – Enhancing care coordination for multimorbid patients through a current care pathway analysis

The need for enhanced care coordination among multimorbid and vulnerable patients is widely recognised. However, the current healthcare system predominantly focuses on single diseases, often resulting in inadequate evaluation and management of coexisting morbidities. Consequently, this approach leads to suboptimal care, inefficiencies, duplications, and compromised quality of care. Various strategies have been developed to address the care needs of older multimorbid patients, but they vary across different countries.

As part of the preliminary analysis and WP3 tasks before the implementation of GERONTE, Bocconi recently conducted an analysis of the care pathway for older multimorbid cancer patients to gain insights into the current practices followed by the 16 clinical sites participating in the trial.

A total of 39 semi-structured interviews were conducted with key stakeholders (e.g., oncologists, geriatricians, nurses) to delve deep into the analysis of several dimensions, including the organisational context, involvement of healthcare professionals, multidisciplinarity, physical spaces, and organisation of activities.

The ongoing analysis reveals significant variability in the care processes for older multimorbid patients across countries and clinical sites. The organisational context in which each site operates greatly influences its functioning. Three key dimensions are emerging as having a significant impact on the delivery of patient care:

- the scope of services offered by each clinical site within the care pathway,
- the relationships among healthcare professionals, including access to specialised knowledge and
- the availability of tools to facilitate integration among professionals at different stages of the care pathway.

The study highlights the importance of considering the specific characteristics of the organisational context when designing care pathways for older multimorbid patients and determining which change management practices can be implemented in each context. The insights gained from this research project hold promise for shedding light on best practices for effective care coordination and informing future initiatives aimed at improving care for this patient population.

These preliminary results and key lessons will be discussed at two relevant conferences where GERONTE will be represented by Bocconi:

1. <u>The 16th EPH Conference 2023</u> in Dublin, from November 9-11, with a poster on "Care Pathways for Older Multimorbid Patients: Lessons Learned from 16 Clinical Sites in 3 Countries," co-authored by Lucia Ferrara, Vittoria Ardito, Valeria D. Tozzi, Bridget O'Sullivan, Anthony Staines, Paul Davies, Rosanna Tarricone.

2. At the <u>AIES (Italian Health Economics Association)</u> 2023 Annual Conference, which will be held in Rome from December 5-7, 2023, with a paper on "Variability in Care Pathways for Older Multimorbid Cancer Patients: Insights from a Multi-Country Study" co-authored by Lucia Ferrara, Vittoria Ardito, Valeria D. Tozzi, Bridget O'Sullivan, Anthony Staines, Paul Davies, Rosanna Tarricone.







#### Work Package 4 Reporting

Within the GERONTE project, WP4 is responsible for the two identical GERONTE clinical trials, namely FRONE in France and TWOBE in Belgium, which focus on the feasibility and effectiveness of the GERONTE intervention. Approval of the competent authorities for FRONE and TWOBE was obtained in 2022, whereas in 2023, the focus was on the further preparation of both clinical trials, taking all contractual and legal aspects into account and on the development of necessary study documents, e.g., Statistical Analysis Plan, Data Validation Plan, Monitoring Plan, Standard Operating Procedures (SOPs) for both clinical trials. WP4 also supported MyPL over the past year regarding the developing, optimising, and testing the digital tool HolisTM GV. Currently, WP4 is also coordinating the necessary steps for the launch of both FRONE and TWOBE clinical trials, including the online site. Initiation Visits and training of MyPL on the digital tool HolisTM GV. GERONTE clinical trials FRONE and TWOBE are expected to start in late 2023/early 2024.

#### Work Package 5 Reporting

The healthcare of the ageing population is a challenge that continues to grow. GERONTE's goal is straightforward but ambitious: improve the quality of life for older patients grappling with multiple health conditions while simultaneously cutting the cost of care. For the program to create a meaningful impact, effective implementation is crucial. This is where Dublin City University (DCU) comes in, leading the GERONTE Implementation Evaluation. Employing Implementation Science theories and frameworks, DCU aims to identify challenges and develop strategies for rolling out the GERONTE Intervention across Europe. They use a Realist Evaluation approach, meticulously documenting and analysing the complex factors that could affect implementation and, ultimately, the effectiveness of the intervention.

With this in mind, GERONTE has applied to HRB, an initiative of the European Commission which aims to maximise the impact of publicly-funded research within the EU. It goes beyond mere research dissemination, focusing instead on creating a tangible societal impact. It offers free consulting services and supports projects funded by FP7, Horizon 2020 or Horizon Europe programmes.

GERONTE plans to leverage HRB's Service 1, specifically Modules A and C, to enhance its exploitation strategy and business plan. Module A will help identify and create a portfolio of Research & Innovation results, while Module C aims to improve the existing exploitation strategy. These services will be accessed in the last quarter of 2023 and the first quarter of 2024.

Through strategic collaboration with the Horizon Results Booster, GERONTE aims to amplify its impact, ensuring that the research is groundbreaking and practically and sustainably improves the lives of the elderly population it serves. In a rapidly ageing world, such synergies are not just beneficial—they're vital.

### Updates from Dublin City University (DCU)

### Where we are at:

**Baseline evaluation of the challenges, facilitators, and strategies to implementing GERONTE across the trial sites** Dublin City University, which is responsible for the delivery of GERONTE's Implementation Guide and Business Plan in order to support EU-wide uptake of the GERONTE intervention, conducted baseline interviews across the trial sites to identify, describe, and analyse the key challenges, facilitators, and strategies for the implementation of the GERONTE intervention across the clinical trial sites.

In line with GERONTE's objective to maximise the value of research input, the report stemming from this evaluation was shared with GERONTE Partners, including University Bordeaux, KUL, Diak, MYPL and the clinical sites, who put to use this report to provide pre-implementation site-specific preparation and support.

The evaluation drew primarily from pre-implementation interviews with clinicians (Geriatrician, Oncologists, Nurse Specialists) and managers (clinical trial, administrative, business, and technology) to provide site-specific information from professionals experienced in their area. Some supplementary data was drawn from clinical site strategic documents to provide further detail on the clinical sites' service models, structures, and supports. Acknowledgement is given to the many professionals who contributed significant time and information while working in busy clinical environments, to the baseline evaluation.

The evaluation will serve two important functions. It will inform GERONTE's implementation and business guides, providing both site-specific contextual data to enable the development of tailored implementation and business guides. It will also provide a baseline from which to evaluate the broader impact of implementing the GERONTE intervention, change in clinical practices, experience, routines, care, and collaborations at the site.

### **Our next steps**

Dublin City University, in collaboration with GERONTE Partners, will continue to collect baseline data on the site and site preparation as part of the Site Initiation Visits. The focus will now be on identifying the support, training, or other preparation conduction (and why) at each site.

This data will inform the Implementation and Business Guide, in particular, providing detailed and contextualised steps for how to prepare a site for the implementation of GERONTE (a complex technology-supported intervention).

### Presenting GERONTE's work

DCU is preparing to publish generalised materials on the challenges, facilitators, and strategies to implementing complex or technology-supported interventions and the business impact and consideration related to these. DCU's Principal Investigator Prof Anthony Staines, will Chair the European Public Health Conference in November 2023, and will present a poster based on GERONTE work on "Digitally supported health care; evaluation approaches to a complex intervention embedded in a trial", as well as supporting Bocconi's poster presentation from GERONTE's work.



### Work Package 6 Reporting

Following the small-scale pilots, the WP6, as the Work Packages focusing on stakeholders' engagement, started to prepare the materials for the clinical trials, i.e., the training manuals, videos, etc. As the small-scale pilots had shown some minor changes to be made at Holis(<sup>™</sup>) GV, and the partners took some time to ensure that it was put in place by MyPL, the creator of Holis(<sup>™</sup>) GV. Since then, regular meetings between MyPL, UBx, ESE, KUL, and DIAK were held to discuss the outline, structure, and objectives, then progress on the Training Manuals' preparation.

To kick off the clinical trials successfully, the GERONTE consortium has to provide efficient and comprehensive materials to assist stakeholders in getting on board using the developed platform. Drawing on the experience of the small-scale pilots, the WP6 partners identified some frequent questions and blocking points that may hinder smooth onboarding and, consequently, usage of Holis(<sup>™</sup>) GV. Thus, while designing the training support, the partners continuously considered all these aspects to propose solutions for these issues in the tutorial videos and the manuals for the relevant users. Throughout the year, MyPL, UBx, ESE, KUL, and DIAK have worked to design tailor-made manuals for APNs, geriatricians, oncologists, HPC, and patients who experience varied needs and challenges.

#### Dissemination

E-Seniors, the leader of WP6, was invited to participate in AGE.INT, "European Networking Event: Technologies for people in old age," to share its expertise in innovative, assistive technologies for people in old age in November 2022.

#### WELCOME TO THE

European Networking Event: Technologies for people in old age Expertise in innovative, assistive technologies for people in old age





Apart from networking purposes, the event was also aimed at helping the participants discover innovative projects around Europe and present good practice examples such as GERONTE. To interact with the final Holis( $^{m}$ ) GV users, E-Seniors has also participated in numerous forums and events for seniors to promote the project's final result and collect continuous feedback.

# PUBLICATIONS



Nelleke Seghers presenting at Diakonessenhuis's Annual Science Evening

1. Intrinsic capacity and resilience: Taking frailty to the next level by Marije E. Hamaker, Sanne Gijzel, Siri Rostoft and Frederiek van den Bos. (Jan. 2023) DOI: <u>https://doi.org/10.1016/j.jgo.2022.101421</u>

2. Achieving harmony in oncological geriatric assessment – Should we agree on a best set of tools? by Marije E. Hamaker, Petronella A. L. (Nelleke) Seghers, and Siri Rostoft. (March 2023) DOI: <u>https://doi.org/10.1016/j.jgo.2023.101473</u>

3. Achieving harmony in oncological geriatric assessment – Should we agree on a best set of tools? by Pierre Soubeyran, Carine Bellera, and Elena Paillaud (April 2023) DOI: <u>https://doi.org/10.1016/j.jgo.2023.101482</u>

4. Preferred and actual involvement of caregivers in oncologic treatment decision-making: A systematic review, by Laura M.L. Tielemansn Kirsten D. van Heugten, Marije E. Hamaker and Inez C. van Walree (May 2023) DOI: <u>https://doi.org/10.1016/j.jgo.2023.101525</u>

5. Challenges of caring for older patients with multimorbidity including cancer, by Petronella A. L. (Nelleke) Seghers, Pierre Soubeyran, Siri Rostoft, Shane O'Hanlon, Bridget O'Sullivan, Johanneke E. A. Portielje Hans Wildiers and Marije E. Hamaker (July 2023) DOI: <u>https://doi.org/10.1016/j.jgo.2023.101588</u>

6. Geriatric assessment for older people with cancer: policy recommendations by P. A. L. (Nelleke) Seghers, Shabbir M. H. Alibhai, Nicolò Matteo Luca Battisti, Ravindran Kanesvaran, Martine Extermann, Anita O'Donovan, Sophie Pilleron, Anna Rachelle Mislang, Najia Musolino, Kwok-Leung Cheung, Anthony Staines, Charis Girvalaki, Pierre Soubeyran, Johanneke E. A. Portielje, Siri Rostoft, Marije E. Hamaker, Dominic Trépel & Shane O'Hanlon. (September 2023) <u>Open Access</u>

# JOIN GERONTE AT THESE UPCOMING EVENTS

### European Society For Medical Oncology (ESMO) ESMO Congress 2023 20 October, Madrid

ESMO 2023 is a premier congress in medical oncology. The congress attracts an international community of experts across disciplines focused on finding the most effective cancer treatment solutions available today. The congress organisers expect approximately 30,00 participants from around 150 countries. <u>esmo.org</u>



### The International Society of Geriatric Oncology (SIOG) SIOG 2023 Annual Conference 9 November, Valencia

The SIOG Annual Conference offers health professionals an opportunity to take stock of the state of geriatric oncology and shape new partnerships. We invite you to join us in Valencia as we continue to support the worldwide SIOG community with infinite possibilities for progress in geriatric oncology. <u>siog.org</u>





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youtube.com/channel/UCeitImhJi\_eudIXtdBjzxn twitter.com/GERONTEproject <u>w/</u>





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