“AFFIRMO will provide new insights into the management of multimorbidity in patients with atrial fibrillation, the commonest cardiac rhythm disorder. This is important given our ageing society and the increasing public health burden of this condition.”

Professor Gregory Lip

“AFFIRMO integrates insights and expertise across scientific disciplines, health care stake holders and countries in a joint effort to address one of the most pertinent challenges in modern health care: improvement in care for elderly multimorbid patients”

Professor Søren Paaske Johnsen
A NEW AND INTEGRATED APPROACH FOR MULTIMORBIDITY

The AFFIRMO project aims to develop a new clinical pathway for treating older patients with multimorbidity, including Atrial Fibrillation (AF). Multimorbidity is a common condition in older age and can substantially influence people’s health and quality of life, making management more difficult. Meanwhile, AF is the most common heart rhythm disorder, with 1 in 4 adults at risk of developing it in their lifetime and is associated with a higher risk of stroke, death, dementia and heart failure.

The primary approach underpinning AFFIRMO is to identify older patients with multimorbidity (including AF), assess their individual needs, and deliver a holistic, integrated approach to their care that takes account of personal preferences for treatment and considers the social context. **Professor Søren Paaske Johnsen** (Principal Investigator) from the Department of Clinical Medicine at Aalborg University said: “We understand and treat patients better if we look at them from a holistic perspective and see them as human beings with coherent systems of diseases. Otherwise, we simply miss the big picture”. There is a need to focus on the patient’s individual situation and actively involve him in the decision-making process. “That is the great challenge we will address with this project”, concluded Professor Johnsen.

**Professor Gregory Lip** (co-Principal Investigator) from the University of Liverpool said: “Multimorbidity is common in our ageing population, and taking patients with atrial fibrillation (‘AF’) as an example, outcomes are worse with this common heart rhythm problem if multimorbidity is present.

The AFFIRMO project will investigate if a holistic or integrated approach to AF management based on the ABC (Atrial fibrillation Better Care) pathway will improve clinical outcomes in AF patients with multimorbidity.

The five-year AFFIRMO project is being carried out by a multidisciplinary consortium of 20 partners from 9 countries - researchers and clinicians from across Europe representing all research fields essential for the success of this project: clinical research, epidemiology, data science, biostatistics, pharmacology, economics, psychology and social sciences.
THE SCIENCE UNDERPINNING AFFIRMO: THE ABC PATHWAY

When tackling the issues related to elderly patients with Multimorbidity, including Atrial Fibrillation, the AFFIRMO project faces a major challenge: moving from fragmentation to an integrated, patient-centred care strategy. AFFIRMO's answer to this challenge is to develop a holistic care approach based on the Atrial Fibrillation Better Care (ABC) model.

The ABC model was proposed in 2017 to streamline and simplify the management of atrial fibrillation patients. This simple model focuses on three main components:

1. The ‘A’ criterion (Avoid stroke) refers to the management of thromboembolic and bleeding risks by appropriate prescription and use of specific drugs.
2. The ‘B’ criterion (Better symptom management) aims to reduce and control symptom burden by actively involving the patient in the control therapy.
3. The ‘C’ criterion (Cardiovascular and Comorbidity risk optimisation) addresses concomitant comorbidity and cardiovascular risk factors. The aim is to optimise the management of these parallel complications.
Each of the three components is essential to reduce the risk of adverse outcomes in patients with AF. In particular, a recent study on the impact of ABC in patients with AF showed its effectiveness. From a systematic review of clinical studies involving the ABC approach, researchers concluded that the pathway was associated with significantly reducing the risk of adverse outcomes (see the infographic below).

Despite the several advantages associated with the ABC pathway, the adherence to the model is still sub-optimal. Researchers observed that the ABC approach was applied in one of every five AF.

The way to mainstream this approach is still long. AFFIRM project is moving toward this objective by developing a ready-to-deploy solution. Over the next five years, researchers will leverage European resources to deliver a digital and patient-centred approach to manage multimorbidity.
In April 2022, the University of Manchester (UNIMAN), which is part of AFFIRMO’s consortium, has released a report on Software Requirements Specification. The report represents a pivotal step toward the development of a digital platform to facilitate interaction and transmission of care between patients and caregivers. Partners contributing to the elaboration of this new outcome are the following: The European Institute for Innovation through Health Data (i~HD); Aalborg Universitet (AAU); The University of Liverpool (UoL); Universiteit Gent (UGent); Karolinska Institutet (KI); Arrhythmia Alliance (A-A); Istituto Superiore di Sanità (ISS); and the Heart Care Foundation Onlus (HCF).

The purpose of the digital platform is to assist physicians in applying and tailoring the personalized care pathway and promote shared decision-making considering patients’ and caregivers’ needs and preferences. This way, the project’s outcomes will be used in daily clinical practice.
The platform requirements have been classified using the MoSCoW approach and will also be allocated an estimated resource amount which, when combined with the priority of each item, can be used to ensure the iABC platform delivers the highest value requirements. The MoSCoW prioritisation document acts as a living document that can be updated as the project progresses. The MoSCoW approach defines each requirement as one of: Must have, Should have, Could have, Won’t have. “Must have” provides the Minimum Usable SubseT (MUST) of requirements which the project guarantees to deliver. “Should have” are requirements that can be classified as important but not vital. “Could have” are wanted or desirable requirements, nevertheless they are less important than Should have requirements. Finally, “Won’t have” requirements are those which the project team has agreed will not be delivered.

MoSCoW allows clinical and patient representatives to provide regular feedback regarding the priority of existing requirements. In this way, the digital platform is intended to foster the implementation of AFFIRMO’s main goals and develop a patient-centred approach with shared decisions based on the preferences of each person in terms of treatments, lifestyle, psychological wellness, etc., which pays more attention to a variety of factors such as clinical complexity but also social and environmental factors, functional status and cognitive performance of the patient.
THE AFFIRMO'S INTERVENTIONAL STUDY

The first European study testing if a structured digital implemented multilevel care pathway would improve the clinical outcomes and quality of life of elderly patients with AF and multimorbidity.

AF is the most common sustained arrhythmia, associated with a significant morbidity and mortality, due to an increased risk of stroke/peripheral thromboembolism, heart failure, dementia and impaired quality of life. Patients with AF are generally old and with concomitant comorbidities, making their management very complex, characterized by the need of multi-drug prescription. A patient tailored ABC care pathway has been developed to facilitate the management of elderly AF patients with multimorbidity. The ABC pathway focuses on three domains: avoid stroke with Anticoagulation (with optimized VKA or DOAC use); Better symptom management; and optimized management of associated Comorbidities.

A controlled study testing the implementation of an appropriate management of elderly AF patients with multimorbidity in clinical practice (adapting the ABC pathway) versus usual care would provide reliable evidence of an active integrated management approach of this ‘high risk’ clinical condition.

AFFIRMO will use a novel platform (iABC) and will conduct a cluster randomized trial, randomizing centres to iABC versus usual care. Approximately 50 centres from six European countries (Bulgaria, Denmark, Italy, Romania, Serbia, Spain) will include 1250 patients with AF with at least 1 coexisting comorbidity, with the objective to improve the primary outcome of all-cause hospitalizations over a follow-up period of 12 months and quality of life.
The study will be under the responsibility of a Steering Committee (SC) and will be managed and supervised by a Central Coordinating Center (CCC), in Italy, with the help of National Coordinating Centers (NCCs) located in each participating Countries. Between May 2021 and September 2022, the SC of the study in collaboration with CCC and NCCs finalised the protocol and the Case Report Forms (CRFs), that will be used in the study for the electronic data entry. The finalisation of the content of the regulatory package for submission of the study to Country IRBs/Competent Authority in each Country is underway.
In order to develop the empowerment toolbox research has been conducted across Europe through the following steps:

1) systematic analysis of the literature to identify “gold-standards” to measure patient empowerment and to identify evidence-based tools for empowering AF patients;
2) empowerment toolbox to improve patients' ability to seek and use health information, with tools customized according to patients' levels of empowerment;
3) validation interviews with clinicians and patients to optimize the empowerment toolbox.
The literature scan resulted in the identification of 25 validated scales. Only two patient empowerment measures (PHE-S® and PAM®) were identified as adequate tools with consistent psychometric properties. A library of 46 educational materials relevant to patients with AF aimed at increasing their level of empowerment were developed according to the clinical and empowerment profiles of 15 personas. The theory-driven toolbox of validated materials is a valuable instrument to orient healthcare professionals in the personalization of AF patient empowerment interventions. Next step is to implement and test the empowerment toolbox with real-world patients enrolled in the AFFIRMO randomised controlled trial via a bespoke electronic platform.
Over the last year, the AFFIRMO team has put great efforts in participating in scientific events, bringing science closer to the public and increasing awareness on the project. Below are highlighted some of such events.

In October 2021 took place the 17th EuGMS Congress. In this occasion the European Geriatric Medicine Society – which is also part of AFFIRMO’s consortium – had the opportunity to address members of the scientific community and to share information concerning AFFIRMO project and website.

The first Horizon Europe Info Day on Cluster 1 (Health) on June 2021 was an important occasion to meet and engage new potential stakeholders and to remain updated on relevant developments concerning the launch of the new R&I framework programme Horizon Europe. A further Info Day on Cluster 1 was then organized on October 2021. Similar in relevance and size, on June 2021 AFFIRMO attended the European Research and Innovation Days, bringing together policymakers, researchers, entrepreneurs and the public to debate and shape the future of research and innovation in Europe and beyond.
Finally, on May 2022, the project participated in the European Public Health Week 2022. The purpose of the conference was to raise awareness about public health and promote collaboration among the public health community in Europe, and it was another important opportunity to remain updated and to meet and engage new potential stakeholders.

Such conferences and events are an essential activity for the project to foster awareness around AFFIRMO as well as connect with new potentially interested stakeholders, spreading the project’s results and developments among a wider public in order to ensure their best possible exploitation during but also after the project itself.

**In focus: AFFIRMO at the 18th EuGMS Congress in London 2022!**

At the recent annual EuGMS Congress 2022 from the 28th to the 30th of September in London AFFIRMO was represented on various occasions towards a large and international audience composed by geriatricians, health professionals and scientists.
In the morning of the last day of the conference, on the 30th of September, Lu Dai from Sweden provided her lecture with the title “Comorbidity patterns in older adults with atrial fibrillation: a Danish nationwide cohort study” in the course of a well attended oral communications session. With more than 1500 participants at the EuGMS Conference 2022 AFFIRMO gained a lot of international visibility, recognition and potential followers in London and could establish promising further cross-links to other European projects on related topics.
"I am currently a Post-doctoral Research Associate at the “Department of Cardiovascular and Metabolic Medicine” and at the “Liverpool Centre for Cardiovascular Science” of the University of Liverpool. One of the most fascinating aspects of my job is the ability to make a real impact in the life of people, improving the way in which chronic conditions are managed. I personally think that the best achievement that someone can aspire to is to contribute to the Community we are part of, and with my work I hope to help in improving the life of people suffering from health conditions. Nevertheless, working in research means also to face several challenges which force you to think out of the box and try different solutions to reach your target. These challenges may sometimes discourage you, but they are an important part of your personal growth, and are highly educative in making you a better researcher. Resilience is the best virtue you can cultivate, both in life and in Science. I am really enthusiastic to collaborate in the delivery of the Work Package 4 of the AFFIRMO project, as I am sure it will lead to better care for people suffering from Atrial Fibrillation."
"In 2016, as a medical doctor, I received a China Scholarship Council fellowship for an academic visit at Renal Medicine, Karolinska Institutet (KI) where I learned how research activities can support and improve treatment and care for patients. It triggered my interest to continue an academic career. I later started a four-year PhD program at KI in vascular aging in chronic kidney disease and worked as an early stage researcher in Marie Curie research and innovation program INTRICARE(www.intricare.eu), a platform where I had the opportunity to work and collaborate with other enthusiastic scientists from both preclinical and clinical settings. This of Mice and Men research experience strengthens my faith in science and in people, and it drives me to explore with curiosity. I joined to work with AFFIRMO as a postdoc fellow and I am happy to contribute to the development of a holistic and patient-centered integrated care strategy to improve the management of atrial fibrillation with a multidisciplinary and comprehensive effort."

Dr. Lu DAI (Karolinska Institutet)
Field of Expertise: Vascular ageing, ageing epidemiology, diet and microbiome, chronic kidney disease, atrial fibrillation