

Topic idea submitted to IHI - Reference Number: TI_001203

Are you submitting the idea:

- ☐ in your personal capacity?
☒ on behalf of an organisation?

Please select from the list below the type of stakeholders your organization represents: Small & medium enterprise (SME)

1 Title of your idea

Please provide a short title that accurately reflects the objective(s) of your idea:

Anti-Aging Vaccine Development

2 Scope

Explain the specific challenges/problems to be addressed by your idea and how these affect relevant stakeholders, taking into account what is already known and/or available in the field:

The accumulation of senescent cells in various tissues is the underlying cause of major diseases associated with aging, such as type-II diabetes, atherosclerosis, hypertension, and neurodegenerative diseases. These cells have detrimental effects on the body when they chronically accumulate. Aging-related diseases account for ~30% of all global deaths, leading to a diminished quality of life, increased morbidity, and significant healthcare costs.

Current therapies targeting senescent cells are showing promising results, although these are based on genetic interventions (which are either inviable in humans or highly expensive) or chronic treatment with specific drugs (some with side effects or limited efficacy).

Our idea aims to enable the targeted and gradual clearance of accumulated (chronic) senescent cells through the stimulation of the adaptive immune response via vaccine development. The proposed therapy is anticipated to be safer, viable and cheaper, and more specific than the other current approaches.

Given the aging global population, there is an urgent need for new therapies to treat these diseases, as the one proposed here. In addition to natural aging, other conditions associated with senescent cell accumulation and, therefore, beneficiaries of this new therapy include premature aging disorders, cancer patients treated with therapies inducing tumour senescence, and recently, COVID-19 patients. This last case is of special relevance, considering the millions of people infected by SARS-CoV-2 which has been demonstrated induce cellular senescence. In this sense the premature increase of diseases associated with old age in people with long COVID, threaten to collapse National Health Systems in the medium term.

Please indicate which IHI specific objective(s) (SO), as described in the IHI Strategic Research and Innovation Agenda (SRIA), your idea addresses:

["SO2: integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users"]

Please select the keywords that are most relevant to your idea:

["Non-communicable diseases"
"Prevention"
"Treatment"
"Disease management"
"Health technology"]

In alignment with the IHI specific objective(s) selected above, specify the objectives of your idea:

The main goal of this idea is to elicit a specific cytotoxic T-lymphocytes (CTL) immune response to eliminate senescent cells and thus prevent their accumulation and the onset of senescence-related diseases. Two complementary ways will be carried out to achieve the main objective:

-On one hand, based on our preliminary data, analyse the in vivo immunogenicity of several potential T-cell epitopes (vaccine candidates), already selected from various established senescent markers. Those positive peptides will be used in proof-of-concept assays in animals with senescence accumulation.

-On the other hand, develop advanced software (AI) for the identification of new vaccine candidates, integrating search engines such as: i) bibliographic (e.g., PubMed), ii) experimental immunogenicity database, iii) immunogenicity prediction algorithms and iv) protein sequences databases. In this way, this trained AI could rapidly and effectively identify new senescence-associated T-cell epitope candidates, that then would be tested in immunogenicity assays.

3 Expected impacts to be achieved by your idea

Briefly describe the expected impacts to be achieved by your idea, ensuring that they contribute to IHI general and relevant specific objectives, as described in the IHI SRIA:

Impacts are wider long-term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments. Impacts generally occur sometime after the end of the project, e.g. successful implementation of digital solutions supporting people-centred care.

***IHI general objectives:** 1. contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations; 2. foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to 'Europe's Beating Cancer Plan'; 3. drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.*

The expected socioeconomic impact of the idea that we proposed here would be huge, representing an improvement in the quality of life in the following 4 social groups:

-Old people. It is estimated that by the year 2045 the number of people over 60 will surpass the number of people under the age of 15.

-Premature aging diseases' patients. A sector of society with the greatest need for this type of novel therapies.

-Cancer patients treated with agents that induce premature senescence of tumour cells. It is a social group that requires alternative treatments for the elimination of these cells generated during the therapy.

-SARS-CoV-2 infected people. Some of the pathologies associated with a chronic accumulation of senescent cells are similar to those observed in long COVID patients.

In addition, a new AI tool will be generated to search for T-epitopes not only associated with aging, but of general interest.

4 Why should your idea become an IHI call topic?

Explain why collaboration through a cross-sectoral and multidisciplinary public private partnership is needed in particular:

Why does it require collaboration among several industry sectors

(e.g. pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)?

Why does it require collaboration between private (industry) and public partners

(e.g. academia, healthcare practitioners, patients, regulators)?

The present idea is entirely novel and highly ambitious, covering both the private and public sectors. It aims to develop a vaccine based on peptides associated with senescence, capable of inducing a specific and durable immune response. After completing proof-of-concept basic research assays (public sector), the next step would be to scale up the production of vaccine candidates for use in toxicology studies and future clinical trials in humans (pharma, vaccines and public healthcare sectors).

Simultaneously, an AI specifically designed to search for potential T-cell epitopes of any protein whose sequence is available in major databases will be developed. This tool would be developed in the private sector and could be used not only for this project but also for any project requiring the identification of T-cell epitopes to elicit the desired immune response.

Therefore, this idea aligns with the requirements of the IHI topic.

Why is the contribution of industry needed to achieve the expected impacts?

***Contribution of industry:** Large companies that are members of the IHI industry partners (i.e. COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe) contribute to the programme, primarily through 'in-kind' contributions (e.g. their researchers' time, laboratories, data, compounds). At least 45% of each project's total costs have to be in-kind contribution.*

Vaccines are the biomedical breakthrough that has saved the most lives to date and are at the core of this idea. Industry contribution is essential for their development, as it possesses the necessary infrastructure, logistics, and personnel to tackle the whole process, that includes: i) scaling up production, under GMP regulatory framework, of selected vaccine candidates (synthetic peptides) identified in proof-of-concept assays, ii) designing preclinical toxicology studies to rule out adverse effects of our senescence-associated peptides (T-epitopes), and iii) designing the subsequent clinical trials. All of this represents at least 45% of eligible costs, thus aligning with the requirements of the call.