sens research foundation
reimagine aging

project|21 Human Clinical Trials

Project|21 is SENS Research Foundation's ambitious moonshot: a plan to enable human clinical trials of genuine rejuvenation biotechnologies by 2021.

Project|21 will fund three new programs to open the clinical path: the Bridge|21 project to fund the translation of new technologies from research to development; a new Center of Excellence in rejuvenation biotechnology to create new collaboration opportunities, and an Alliance program designed to build a community to address challenges in investment, manufacturing, and regulation.

Why Are Rejuvenation Biotechnology Clinical Trials Critical?

Clinical trials are the most reliable source of clear data to guide health care decision- making. If we are to transform the global biomedical agenda, to embrace the damage-repair approach to aging, and to achieve comprehensive human rejuvenation, we need to demonstrate successful trials in the field. But, there are significant challenges, including these:

- aging and its associated pathologies are the integrated outcome of multiple forms of cellular and molecular damage, and the prevention of any single disease must often be tackled with multiple therapies;
- individual types of damage may relate to multiple pathologies, and so new ways to measure and understand efficacy may need to be developed; and
- rejuvenation is by its nature preventive, and may require that we develop and rely on biomarkers of age-related damage, rather than an immediate assessment of a patient's disease state.

Such barriers to human clinical trials stall investment and slow development and they will only begin to be addressed once multiple rejuvenation trials start in earnest. Therefore, we have designed Project|21 to assist industrial players in crossing that chasm. Below are several examples of how our programs are already helping build the bridge.

How Will SENS Research Foundation Enable Human Clinical Trials by 2021?

Using translationally-focused funding to promote early technology transfer, and ***curing blindness***

Both the loss of light-sensing cells in the eye due to age and the debris that they leave behind ultimately lead to age-related macular degeneration (ARMD), the leading cause of blindness in people over the age of 65. Scientists in our Research Center have identified enzymes that could enable cells to clear themselves of these toxins, making them candidates for potential development into rejuvenation biotechnologies for the prevention and cure of ARMD. Through our technology transfer program, SRF has licensed this early-stage work to Ichor Therapeutics, a rejuvenation biotechnology startup, just one example of advancing relevant science while creating opportunities for new players in the private market.

Providing bridge funding to promote early private development, and thereby ***restoring immune function***

Dysfunctional, damaged cells accumulate in aging tissues and secrete growth factors, tissue-degrading enzymes, and inflammatory molecules that reduce immune function and facilitate the growth of cancer. To help solve this problem, SRF has invested in an innovative approach at Oisín Biotechnologies for the specialized targeting of these senescent cells. Early on, interventions to purge aging tissues of accumulated senescent cells could be used to reduce the risk of cataracts, to prevent and treat osteoarthritis, and restore immune function. Downstream, regular clearance of these cells would help to keep multiple systems across the body healthy and functioning, making them a key contributor to multiple combinatorial damage-repair protocols.

Building Center of Excellence collaborations and ***treating Alzheimer's disease***

Two lesions in the aging brain are the hallmarks and key drivers of Alzheimer's disease. One is beta-amyloid, a protein that accumulates in plaques outside of cells. Rejuvenation biotechnologies based on antibodies that bind to beta-amyloid and remove the sticky aggregates from the brain are already in human clinical trials. To be successful in rescuing the brain from age-related degeneration, we must also develop therapies to tackle aberrant tau, which is the key lesion inside the brain cells in Alzheimer's and which is more closely linked to brain cell death. As young brain cells may be fully capable of degrading these aggregates, it is possible that this ability is lost as we age due to impairments in the lysosome, the cell's "incinerator" for such wastes. Identification of this impediment, and the application of our lysoSENS enzyme strategy to clear it and restore robust lysosomal function, will be the subject of collaborative research in our new Center of Excellence.

Funding long-range research and ***preventing cardiac amyloidosis:*** Under Project|21, SRF will continue to fund basic research that receives little or no attention from government funding programs. One such program is in transthyretin (TTR) aggregates, compounds that accumulate in the aging heart and other organs, contributing to heart failure and mortality in the very elderly. SRF funded basic research at the University of Texas-Houston enabling the identification and optimization of catalytic antibody fragments (capable of cleaving TTR aggregates) in human plasma. The team we funded has begun development through a private company, Covalent Biosciences.

Help Us Deliver Human Clinical Trials by 2021

Rejuvenation Biotechnology offers the promise to transform the efficiency and efficacy of healthcare for aging patients. But it desperately needs a push. We will do everything we can to move the science forward, create an efficiently cooperating industry, help build an appropriate regulatory structure, and, in the end, enable genuine clinical trials in this field by 2021. To get there we need the support of all our stakeholders. Please help us make this vision a reality.

To learn about SENS Research Foundation's Project|21, and how you can help, go to www.SENSProject21.org.

project|21

Building the Bridge to Human Clinical Trials for Rejuvenation Biotechnologies

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