The ONE Study

At a Glance

- Status: Active Consortium
- Year Launched: 2011
- Initiating Organization: European Commission Seventh Framework Programme (FP7)
- Initiator Type: Government
- Location: Europe

Research Areas

- Tool Development
- Basic Research

Abstract

ONE Study aims to produce regulatory T cells that are compatible with a kidney transplant patient’s immune system, as a measure to suppress the body’s natural immune response against a transplanted organ. If successful, then this approach will reduce a transplantation patient’s life-long dependency on immune-suppressing drugs, many of which are often associated with undesirable side effects and can limit the patient’s daily routine.

Mission

ONE Study aims to reduce the need for immunosuppression drugs that prevent the rejection of transplanted organs. Current immunosuppression drugs require long-term administration, many of which could result in severe toxic side effects — including chronic kidney graft failure, infections and cancer — imparting both a financial and lifestyle hardship to transplant patients. The consortium goals are to develop and conduct clinical trials of various immunoregulatory T-cell-based products in organ transplantation recipients, allowing a direct comparison of the safety, clinical practicality, and therapeutic efficacy of each cell type.
The different work streams include the following:

The second work stream focuses on designing and conducting a cell therapy–based clinical trial in renal transplantation, taking into consideration ethics, concurrent immunosuppressive drug use, state-of-the-art immune monitoring, innovative “all-in-one” data-capturing systems, and pharmacovigilance. The goal is to have a comparative evaluation of hematopoietic cell therapy safety in renal transplantation.

Consortium History

ONE Study objectives were planned by Edward K. Geissler, from the Department of Surgery at the University Hospital Regensburg. He currently serves as the project coordinator and was responsible for convening the other partners and pursuing funding from the European Commission to formalize the consortium.

Structure & Governance

ONE Study is led by a project coordinator, a professor from University of Regensburg. The Steering Committee provides oversight to the technical and operational subgroups powering the consortium. In addition to these committees, there is also an External Advisory Board.

The Project Ethics Committee (PEC) provides advice in clinical trial design. The PEC reviews all aspects of the clinical trial design, has been present at key meetings, and will provide a statement regarding ethics to regulatory authorities as ONE Study moves closer to the cell therapy trial.

Financing

The European Commission contributes €10.8 million through the Seventh Framework Programme (FP7), with in-kind contributions totaling €4 million from the consortium participants. The official title of the project is “A Unified Approach to Evaluating Cellular Immunotherapy in Solid Organ Transplantation.”
Intellectual Property

Specific details about the intellectual property (IP) rights for this consortium were not available. General principles for IP rights for all FP7-supported projects can be found here. In general, all IP generated as a result of the consortium belongs to the inventor(s). Agreements need to be signed before the launch of the consortium. The European Commission has the discretion to protect any IP, if the consortium participants decide not to pursue any protection.

Patent Engagement

No patient groups were identified as part of the governance boards.

Data Sharing

Details about a formal data-sharing platform were not available. Most of the communications between participants are through subgroups, committees, publications, and face-to-face meetings (including the annual meeting).

Impact/Accomplishment

During the first three years of the project, the main activity of the clinical research centers has been the preparation of the clinical protocols for the Reference Group Trial and the submission of IMPD (Investigational Medicinal Product Dossier) and IND (Investigational New Drug) to the regulatory agencies for the cell therapy trials, as well as the development of a centralized immune monitoring program. The Loughborough and ESI partners have shown, in cooperation with the Oxford and Regensburg groups, that regulatory cells can be labeled (gadolinium or gold particles) and detected at a very low frequency.

Links/Social Media Feed
Points of Contact

Edward K. Geissler, Ph.D.
University of Regensburg, Germany
Department of Surgery
University Hospital Regensburg
Franz-Josef-Strauss-Allee 11
93053 Regensburg, Germany
phone: +49 941 944 6964 or 6961

Sponsors & Partners

ALTA Srlu
Beckman Coulter Life Science
Charite, Germany
Electro Scientific Industries
Fondazione Centro San Raffaele
King’s College London
KOELER eClinical
Massachusetts General Hospital
Miltenyi Biotec GmbH
Nantes University Hospital
Pharmatching GmbH
University of California, San Francisco
University of Loughborough
University of Oxford
University of Regensburg
University of Wisconsin

Updated: 04/15/2016