

Critical Path Institute Launches Transplant Therapeutics Consortium

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Tucson, Ariz., April 26, 2017 –[Critical Path Institute](#) (C-Path) is pleased to announce the launch of the Transplant Therapeutics Consortium (TTC), co-founded by the two leading US organizations in organ transplantation: the [American Society of Transplantation](#) (AST) and the [American Society of Transplant Surgeons](#) (ASTS). The TTC is a collaboration within the transplant community including clinicians, surgeons, industry scientists, and others. The overall objective of the TTC is to collaborate on the development and regulatory endorsement of new drug development tools applicable in kidney transplant, with the hope of expanding to other solid organ transplantation in the future.

In the United States, there are currently 600,000 patients receiving dialysis every year, with more than 105,000 patients on the kidney transplant waiting list. In 2016, there were 19,000 kidney transplants in the US, and the failure rates for living donor kidney transplants at 1, 5, and 10 years are approximately 3%, 15%, and 40%, respectively. Deceased donor kidney transplant failure rates are even higher, with 8%, 27%, and 53% of these transplants failing at 1, 5, and 10 years, respectively (https://www.usrds.org/2016/view/v2_07.aspx). Developing new immunosuppressive therapies that can reduce long-term kidney transplant failure will ensure that fewer patients receive multiple transplants, and that more patients on the waiting list can receive a kidney.

“As demonstrated in other therapeutic areas of unmet need, the use of standardized datasets from a broad number of stakeholders informs the development of biomarkers, outcome assessment measures, and other novel tools that regulatory authorities may endorse. Ultimately, the incorporation of these new methods and tools into drug development programs will increase the likelihood of success in getting safe and effective therapies to transplantation patients,” said C-Path President and CEO Dr. Martha Brumfield.

The three areas of focus for TTC include: (1) translating immunosuppressive therapies from other therapeutic areas to transplantation, (2) evaluating a number of candidate biomarkers for kidney transplant failure, with the objective of identifying those most likely to inform innovative clinical trial design and seeking regulatory endorsement, and (3) exploring methodologies that are capable of effectively incorporating the voice of the

patient into clinical trial design. The sharing of knowledge, expertise, and data will be critical to the success of each of these TTC goals.

“Due to the number of patients waiting for a kidney, the initial goal of the TTC will be to focus on kidney transplantation. The TTC will aim to improve outcomes for kidney transplant recipients, lower kidney transplant failure risks, and reduce the need for multiple transplants. The hope is to expand to other solid organ transplantation in the future,” said AST President Anil Chandraker, MD.

“The challenge of introducing new immunosuppressive therapies for the transplant population is becoming increasingly difficult. Severity of illnesses and underlying comorbidities, and limited numbers of patients with endpoints that are in continual evolution, makes the design, administration, and regulation of clinical trials increasingly difficult. It is our hope that the TTC will address these issues at their core and reduce barriers for the effective and safe use of new agents that benefit our patients,” said Timothy L. Pruett, MD, President of ASTS.

About the Organizations:



Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the US Food and Drug Administration (FDA). C-Path’s mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established 14 global, public-private partnerships that currently include over 1,450 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit www.c-path.org.



The **American Society of Transplantation (AST)** is an organization of more than 3,500 professionals dedicated to advancing the field of transplantation and improving patient care by promoting research, education, advocacy, and organ donation. The society is the largest organization of transplant professionals in North America. AST members are sought out as transplant experts and advocates. Other transplant organizations, policymakers, regulatory agencies, payors, academic institutions, and the general public look to the AST for guidance, research, and resources related to transplantation.



The **American Society of Transplant Surgeons (ASTS)** represents approximately 1,800 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through leadership, advocacy, education, and training.

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