



## Creating Global Collaborative Opportunities



### IMMUNE TOLERANCE NETWORK

The Immune Tolerance Network (ITN) is an international clinical research consortium funded by the National Institutes of Health, with additional support from the Juvenile Diabetes Research Foundation. The ITN's mission is to accelerate the clinical development of immune tolerance therapies.



The ITN develops and conducts trials of novel immune tolerance therapies for Type 1 diabetes and other autoimmune diseases, solid organ and islet transplantation, and allergies and asthma. While safety and efficacy are the utmost goals for the trials, the ITN also actively investigates the mechanisms of tolerance induction and maintenance by integrating hypothesis-driven, mechanism-based research and biomarker discovery into all of its clinical trials.

### Our Goals

To identify and develop treatment "game changers" for tolerance modulating therapies for the treatment of immune mediated diseases and disabling conditions.

To conduct high quality, innovative clinical trials and mechanistic studies not likely to be funded by other sources or to be conducted by private industry that advance our understanding of immunological disorders.

### Why partner with the ITN?

In the ITN's unique hybrid academic/industry model, the areas of academia, government and industry are integral to planning and conducting clinical studies. We develop and fund clinical trials and mechanistic studies in partnership.

Our development model is a unique, interactive process. It capitalizes on our wide-ranging, multidisciplinary expertise provided by an advisory board of highly respected faculty from institutions world-wide. This model gives investigators special insight into developing high quality research studies.



The ITN is comprised of leading scientific and medical faculty from more than 50 institutions in nine countries worldwide and employs over 80 full-time staff at the University of California San Francisco (UCSF), Bethesda, Maryland and Benaroya Research Institute in Seattle, Washington.

**THE BEDSIDE IS THE BENCH.**

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## Strategic Collaborations with Industry

The ITN is looking for opportunities to collaborate with industry in strategic alliances that will advance the goals of all of the partners. Areas of interest for the ITN include:

- Companies developing immune tolerance modifying therapies that could benefit from the ITN's expertise and infrastructure in developing clinical protocols and executing Phase I and II studies.
- Areas where the ITN clinical trials could extend the current indications of therapies into new diseases or conditions with small markets. We want to provide proof of concept in humans for novel mechanisms of action.
- Opportunities for the ITN to conduct combination studies with other known or experimental agents that could lead to novel therapeutic strategies. We seek to facilitate the transition from preclinical studies to first in human clinical trials.
- Places where ITN biomarker and mechanistic studies can complement companies' research or ongoing/planned clinical trials. This would be achieved through the ITN Core Laboratories with validated standards of operation and methodologies for controlled collection, storage, shipment, testing, and analysis of assays such as flow cytometry and gene expression profiling.



### The ITN provides:

- The expertise and infrastructure to develop clinical protocols and to execute Phase I and II studies. The ITN has completed or is conducting over 30 clinical trials over the past 10 years. For more information, visit: [www.immunetolerance.org/professionals/research/clinical-trials](http://www.immunetolerance.org/professionals/research/clinical-trials)
- Validated processes and core laboratories with the expertise to execute quality biomarker and mechanistic studies. The ITN utilizes 13 centralized, standardized core assay facilities to conduct this research. For more information, visit: [www.immunetolerance.org/professionals/research/core-facilities](http://www.immunetolerance.org/professionals/research/core-facilities)

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### ITN HAS 10 YEARS OF EXPERIENCE

COMPLETED TRIALS: **15**

OPEN TRIALS: **15**

NUMBER OF CLINICAL SITES: **62**

NUMBER OF PATIENTS  
ENROLLED: **2,598**

NUMBER OF CORE  
LABORATORY FACILITIES: **13**

NUMBER OF SAMPLES  
IN THE REPOSITORY: **273,856**

NUMBER OF PATIENTS FREE  
FROM IMMUNOSUPPRESSION: **23**

NUMBER OF CONCEPT  
PROPOSALS REVIEWED: **340**

