



The bedside **is** the bench.





## A new paradigm for clinical research in immunology.

**Innovation.** With meticulously planned clinical protocols of leading-edge therapies and highly standardized, state-of-the-art biological assays, the ITN is generating some of the first clinical and mechanistic data on immune tolerance induction in humans.

**Integration.** The ITN looks beyond the traditional clinical trial endpoints of safety and efficacy, actively investigating the mechanisms of tolerance induction and maintenance in humans and seeking to define new biomarkers of tolerance.

**Interactivity.** The ITN development model is a highly interactive process that capitalizes on our wide-ranging, multidisciplinary expertise. It begins with the application process - from pre- and post-application support, to formal Q&A sessions with reviewers, we help investigators develop research studies of the highest quality.

**Partnership.** In the ITN's unique hybrid academic/industry model, academia, government and industry all play a vital role the conduct and planning of clinical studies. With a flexible partnership model, the ITN acts as a catalyst to help each partner meet their own individual research goals.

# Accelerating clinical tolerance induction by fusing leading-edge clinical trials with mechanism-based science.

**Uncommon Experience.** Currently supporting over 20 clinical trials of emerging tolerance strategies, the ITN has unprecedented experience in the field. We have a demonstrated ability to navigate the special design and regulatory issues associated with early trials of tolerance therapies. A few of our notable accomplishments:

- ◆ safe, approved protocols in transplantation aiming for complete immunosuppressive withdrawal
- ◆ quickly enrolled and completed high-impact multicenter studies of novel tolerance agents in allergic rhinitis
- ◆ completed several trials of potential tolerizing agents in type 1 diabetes, MS and other autoimmune diseases

**A Systematic Approach.** Built into the protocol of each ITN clinical trial is a complementary set of genetic, cellular and immunological studies that explore the underlying mechanisms of tolerance and disease. With a rich array of established core facilities and the ability to quickly validate and implement additional custom-designed assays as required, ITN clinical trials are defining a new integrated approach to clinical research.

**Comprehensive Support:** The ITN supports its investigators by providing wide-ranging expertise and support for:

- ◆ Protocol design
- ◆ Regulatory approval
- ◆ Collaborators/clinical site identification
- ◆ Mechanistic study design
- ◆ Site training
- ◆ Patient recruitment
- ◆ Protocol monitoring
- ◆ Data acquisition
- ◆ Bioinformatics/Data analysis

**Exceptional Data Quality.** By employing centralized assay facilities at world-leading laboratories, inter-laboratory variation is eliminated and direct data comparisons are possible across all clinical sites - even between trials. Standard Operating Procedures based upon optimized, rigorously quality-controlled protocols are used ITN-wide to ensure highly reproducible results. Automated tracking and storage of clinical specimens allows blinded analyses and the opportunity to perform additional assays at a later date.

**Robust Data Analysis.** Centralized data warehouses and a fully-staffed data analysis unit provide virtually unlimited degrees of freedom in analyzing data from ITN studies. From simple statistical tests to sophisticated bioinformatics tools, powerful genetic analyses and multiparametric tests, flexibility is at the heart of the ITN data analysis strategy. New tools and mining techniques for exploring mechanistic data in the context of clinical outcomes allow investigators to uncover the hidden meaning in their data.

**Funding & Support:** Support is available to academic, industry and government investigators for novel single or multicenter phase I/II clinical trials and integrated mechanistic studies of tolerance-inducing strategies in:

- ◆ **transplantation**
- ◆ **autoimmune diseases**
- ◆ **allergy & asthma**

Short, 5-page 'concept proposals' are accepted on-line, anytime with no submission deadline at [www.immunetolerance.org](http://www.immunetolerance.org).

## Good thinking. Better research.

### More than just a simple funding agency...

From initial application through data analysis, the ITN stands behind its investigators, providing unparalleled scientific expertise and comprehensive clinical, laboratory and administrative resources.

### More than a clinical research consortium...

With a unique, hybrid academic-industry model and an unprecedented array of laboratory resources, the ITN integrates hypothesis-driven, mechanism-based research into all its clinical trials. At the ITN, the bedside *is* the bench.

### A platform for innovation.

Immune tolerance therapies have endless possibilities to impact human health. With a fresh approach to clinical research, wide-ranging expertise and comprehensive clinical and laboratory resources, the ITN turns good ideas into great results.



Immune Tolerance Network  
Suite 300 - 3333 California St  
San Francisco, CA 94118

Online: [www.immunetolerance.org](http://www.immunetolerance.org)

*The Immune Tolerance Network is sponsored by the  
National Institute of Allergy and Infectious Diseases.*

*Additional support provided by the National Institute  
of Diabetes & Digestive & Kidney Diseases and  
the Juvenile Diabetes Research Foundation.*