

BISC/ImmPort Data Release 14 studies

June 2015

Global Updates: Edits were made to file names to ensure uniqueness.

Study Program: Bioinformatics Approach to Influenza A/H1N1 Vaccine Immune Profiling

Title: Bioinformatics Approach to Influenza A/H1N1 Vaccine Immune Profiling

Accession: SDY67

Subjects: 159

Study PI, contact: Gregory Poland M.D., Mayo Clinic, Rochester, MN

Study Description: Using healthy adults between the ages of 50-74, vaccinated with 2010-2011 trivalent influenza vaccine, characterize human immune profiles across time and correlate the profiles with vaccine immunogenicity

Publication: The Impact of Immunosenescence on Humoral Immune Response Variation after Influenza A/H1N1 Vaccination in Older Subjects. *PLoS One*. 2015 Mar 27;10(3):e0122282. doi: 10.1371/journal.pone.0122282. [[PubMed](#)]

Assays in ImmPort:

Assay Type	Number of Exp. Samples
Array	476
ELISPOT	477
Flow Cytometry	4023
Meso_Scale_Discovery	1272
Hemagglutination Inhibition	1272
Q-PCR	625
Virus Neutralization	635

Clinical Assessments in ImmPort: none

Notes: New study

Study Program: Immune Tolerance Network

Title: AbATE ITN027AI: Autoimmunity-blocking Antibody for Tolerance in Recently Diagnosed Type 1 Diabetes

Accession: SDY524

Subjects: 83

Study PI, contact: Kevan Herold, Yale University, New Haven, CT

Study Description: Anti-CD3 monoclonal antibody (a.k.a. hOKT3gamma1 [Ala-Ala], teplizumab, MGA031) is a humanized antibody that is commonly used to prevent organ rejection. The purpose of this study is to determine whether anti-CD3 mAb treatment can halt the progression of newly diagnosed type 1 diabetes.

Publication: Teplizumab (anti-CD3 mAb) treatment preserves C-peptide responses in patients with new-onset type 1 diabetes in a randomized controlled trial: metabolic and immunologic features at baseline identify a subgroup of responders. *Diabetes*. 2013 Nov;62(11):3766-74. doi: 10.2337/db13-0345.

[[PubMed](#)]

Assays in ImmPort: none

Clinical Assessments in ImmPort: adverse events, concomitant medications, auto-antibody

Notes: New study

Study Program: Immune Tolerance Network

Title: IL2-RAPA ITN018AI: Proleukin and Rapamune in Type 1 Diabetes Mellitus

Accession: SDY565

Subjects: 9

Study PI, contact: Carla Greenbaum, Benaroya Research Institute, Seattle, WA

Study Description: This study will evaluate whether treatment of type 1 diabetes patients with Proleukin and Rapamune can halt the destruction of beta cells.

Publication: Rapamycin/IL-2 combination therapy in patients with type 1 diabetes augments Tregs yet transiently impairs β -cell function. Diabetes. 2012 Sep;61(9):2340-8. doi: 10.2337/db12-0049. [[PubMed](#)]

Assays in ImmPort:

Assay Type	Number of Exp. Samples
Flow cytometry	211

Clinical Assessments in ImmPort: c-peptide area under curve, demethylation data

Notes: New study

Study Program: Immune Tolerance Network

Title: Shapiro ITN005CT: Islet Transplantation in Type 1 Diabetic Patients

Accession: SDY567

Subjects: 34

Study PI, contact: James Shapiro, University of Alberta, Edmonton, Alberta, Canada

Study Description: Phase 1, single-arm study testing whether islet transplantation procedures and results from a previous study conducted in Edmonton, Canada, can be repeated.

Publication:

- Portal vein thrombosis complicating islet transplantation in a recipient with the Factor V Leiden mutation. Transplantation. 2004 Jul 15;78(1):172-3.. [[PubMed](#)]
- International trial of the Edmonton protocol for islet transplantation. N Engl J Med. 2006 Sep 28;355(13):1318-30... [[PubMed](#)]

Assays in ImmPort: none

Clinical Assessments in ImmPort: adverse events, diabetes assessment, blood chemistries, insulin administration, immunosuppressant levels, etc...

Notes: New study

Study Program: Immune Tolerance Network

Title: Orban ITN012AI: Evaluation of Diabetes Vaccine IBC-VSO1 in Newly Diagnosed Diabetics

Accession: SDY568

Subjects: 12

Study PI, contact: Tihamer Orban, Joslin Diabetes Center, Boston, MA

Study Description: IBC-VSO1 vaccine, a synthetic metabolically inactive form of insulin is being evaluated as means of preventing pancreatic beta-cell destruction in newly diagnosed type 1 diabetes patients.

Publication: Autoantigen-specific regulatory T cells induced in patients with type 1 diabetes mellitus by insulin B-chain immunotherapy. J Autoimmun. 2010 Jun;34(4):408-15. doi: 10.1016/j.jaut.2009.10.005. [[PubMed](#)]

Assays in ImmPort: none

Clinical Assessments in ImmPort: adverse events, concomitant medications, diabetes history, HbA1c, etc...

Notes: New study

Study Program: Immune Tolerance Network

Title: Herold II ITN007A1: Treatment with hOKT3-gamma-1 (Ala-Ala) in Type 1 Diabetes Mellitus

Accession: SDY569

Subjects: 11

Study PI, contact: Kevan Herold, Yale University, New Haven, CT

Study Description: This is a phase II study examining clinical and immunological effects of humanized FcR non-binding anti-CD3 mAb in participants with Type 1 diabetes mellitus (T1DM), and to develop this therapy to prevent immune destruction leading to beta cell loss.

Publication: none

Assays in ImmPort: none

Clinical Assessments in ImmPort: adverse events, concomitant medications, rubella titer, diabetes history, medical history, etc...

Notes: New study

Updates

Study Acc	Study Title	Update
SDY91	RAVE ITN021A1 Rituximab for the Treatment of Wegener's Granulomatosis and Microscopic Polyangiitis	Updated all study files
SDY167	VRC304 – A Phase I Study of the Safety and Immunogenicity of a Recombinant DNA Plasmid Vaccine (VRC-AVDNA036-00-VP) Encoding for the Influenza Virus H4 Hemagglutinin Protein in Healthy Adults	Adverse Events parsed, mapped to MedDRA
SDY210	Asthma Control Evaluation (ACE): A Biomarker-Based Approach to Improving Asthma Control and Mechanistic Studies	Adverse Events parsed, mapped to MedDRA
SDY211	Inner-City Anti-IgE Therapy for Asthma	Adverse Events parsed, mapped to MedDRA
SDY223	A Biomarker-based Pilot Study of Cockroach Sublingual Immunotherapy in Cockroach Sensitive Adults with Asthma and/or Perennial Allergic Rhinitis	Adverse Events parsed, mapped to MedDRA