



# BIOSPECIMEN and DATA RESOURCES

## **BLOOD DISEASE AND TRANSFUSION MEDICINE**

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#### Anti-HIV Immunoglobulin in Prevention of Maternal-Fetal HIV Transmission: Pediatric AIDS Clinical Trials Group protocol 185 (PACTG)

Clinical Trial 1991 - 1997

Resources: Data, Cells, Isolates from Culture, Plasma

PACTG was a controlled Phase III trial designed to determine if HIVIG given to HIV-positive pregnant women during the second and third trimester of pregnancy reduced the likelihood of maternal-fetal HIV transmission.

#### **Blood and Marrow Clinical Trials Network (BMT CTN) Resources**

The BMT CTN was established in October 2001 to conduct large multi-institutional clinical trials and address important issues in hematopoietic stem cell transplantation in order to enhance treatment approaches.

Blood and Marrow Clinical Trials Network (BMT CTN) A Multi-Center Biologic Assignment Trial Comparing Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients with Intermediate-2 & High Risk Myelodysplastic Syndrome (1102) Hypomethylating Therapy or Best Supportive

Clinical Trial

December 2013 - October 2021

Resources: Data only

The BMT CTN-1102 study was designed to evaluate the relative benefits of reduced intensity conditioning allogeneic HCT compared to non-transplant therapies in older patients with higher-risk myelodysplastic syndrome.

Blood and Marrow Clinical Trials Network (BMT CTN) A Multi-Center, Phase II Trial of Non-Myeloablative Conditioning (NST) and Transplantation of Umbilical Cord Blood (UCB) From Unrelated Donors in Patients With Hematologic Malignancies (0604)

Clinical Trial

January 2009 - April 2011

Resources: Data only

BMT CTN 0604 examine the safety and effectiveness of a non-myeloablative stem cell transplant using umbilical cord blood as a treatment option for patients with leukemia or lymphoma and no suitable related donor.

Blood and Marrow Clinical Trials Network (BMT CTN) A Multi-Center, Phase III, Randomized Trial of RIC, and Transplantation of (dUCB) Versus HLA-Haplo Related Bone Marrow for Patients with Hematologic Malignancies (1101)

Clinical Trial

June 2012-September 2020

Resources: Data only

BMT CTN 1101 compared the effectiveness of two new types of bone marrow transplants in people with leukemia or lymphoma: one that uses bone marrow donated from family members with only partially matched bone marrow (haplo-BM); and one that uses two partially matched cord blood units (dUCB).

Blood and Marrow Clinical Trials Network (BMT CTN) A Multi-Center, Randomized, Double Blind, Phase III Trial Evaluating Corticosteroids with Mycophenolate Mofetil vs. Corticosteroids with Placebo as Initial Systemic Treatment of Acute GVHD (0802)

Clinical Trial

January 2010 to June 2013

Resources: Data only

BMT\_CTN 0802 explored the difference in response and survival rates for individuals with acute graft versus host disease who received mycophenolate mofetil plus corticosteroids versus corticosteroids alone.

Blood and Marrow Clinical Trials Network (BMT CTN) A Multi-center Phase II Trial Randomizing Novel Approaches for Graft-versus-Host Disease Prevention Compared to Contemporary Controls (1203)

Clinical Trial

August 2014 - October 2017 Resources: Data only

The BMT CTN 1203 trial was initiated to evaluate three novel approaches for graft-versus-host disease prophylaxis compared to a contemporary control.

Blood and Marrow Clinical Trials Network (BMT CTN) A Phase II Trial of Non-Myeloablative Allogeneic Hematopoietic Cell Transplantation for Patients With Relapsed Follicular Non-Hodgkin's Lymphoma Beyond First Complete Response (0701)

Clinical Trial

April 2009 - August 2016

BMT CTN 0701 evaluated the effectiveness of reduced intensity conditioning in the procedure called non-myeloablative allogeneic blood stem cell transplant for people with relapsed follicular non-Hodgkin's lymphoma.

lood and Marrow Clinical Trials Network (BMT CTN) A Phase III Randomized, Multicenter Trial Comparing Sirolimus/Tacrolimus With Tacrolimus/Methotrexate as Graft-versus-Host Disease Prophylaxis After HI

Clinical Trial

November 2006 - October 2015

Resources: Data, Plasma, Serum, WBC Pellets

BMT CTN 0402 investigated if the combination of tacrolimus and sirolimus (Tac/Sir) was more effective than tacrolimus and methotrexate (Tac/Mtx) in preventing acute graft-versus-host disease and early mortality after allogeneic related donor hematopoietic cell transplantation.

Blood and Marrow Clinical Trials Network (BMT CTN) A Randomized, Phase II, Multicenter, Open Label, Study Evaluating Sirolimus and Prednisone in Patients With Refined Minnesota Standard Risk, Ann Arbor 1/2 Confirmed Acute Graft-Versus-Host Disease (1501)

Clinical Trial

October 2016 - February 2019

Resources: Data only

The BMT CTN 1501 study was initiated to estimate the difference in day 28 complete response/partial response rates for sirolimus vs prednisone as initial treatment of patients with standard risk acute graft-versus-host disease.

Blood and Marrow Clinical Trials Network (BMT CTN) A Trial of Tandem Autologous Stem Cell Transplants +/- Post Second Autologous Transplant Maintenance Therapy Versus Single Auto ogous Stem Cell Transplant Followed by Matched Sibling Non-myeloablative Allogeneic Stem Cell Transplant for Patients With Multiple Myeloma (0102)

Clinical Trial

December 2003 - March 2013

Resources: Data, DNA, Peripheral Blood Mononuclear Cells, Serum, Stem Cells

BMT CTN 0102 compared progression-free survival of patients with multiple myeloma biologically assigned to receive autologous hematopoietic cell transplantation followed either a second auto HCT or by allogeneic transplantation. Patients within the tandem autologous transplantation arm were randomized to receive one year of maintenance therapy with thalidomide plus dexamethasone or observation.

Blood and Marrow Clinical Trials Network (BMT CTN) Allogeneic Hematopoietic Cell Transplant for Hematological Cancers and Myelodysplastic Syndromes in HIV-Infected Individuals (0903)

Clinical Trial

September 2011-November 2016

Resources: Data only

The BMT CTN 0903 study assessed the feasibility and safety of allogeneic hematopoietic cell transplantation in HIV-infected patients. The primary endpoint was 100-day non-relapse mortality.

Blood and Marrow Clinical Trials Network (BMT CTN) Bone Marrow Transplant From Partially Matched Donors and Nonmyeloablative Conditioning for Blood **Cancers (0603)** 

Clinical Trial

October 2008 to November 2013

Resources: Data only

BMT CTN 0603 compared survivorship of recipients who received a bone marrow transplant, using the reduced intensity conditioning transplant technique, from a related and partially matched donor. This trial ran in parallel with BMT CTN 0604.

Blood and Marrow Clinical Trials Network (BMT CTN) Calcineurin Inhibitor-Free Interventions for Prevention of Graft-versus-Host Disease (1301)

Clinical Trial

August 2015 - October 2020 Resources: Data only

The purpose of the BMT CTN 1301 study was to compare chronic Graft-versus-Host Disease after hematopoietic cell transplant between two calcineurin inhibitor free interventions and a tacrolimus/methotrexate control in patients with HLA-matched donors.

Blood and Marrow Clinical Trials Network (BMT CTN) Comparing Peripheral Blood Stem Cell Transplantation Versus Bone Marrow Transplantation in Individuals With Hematologic Cancers (0201)

Clinical Trial

January 2004 - April 2014 Resources: Data, Plasma, Serum

BMT CTN 0201 compared survival rates of patients with hematologic cancers that received transplantation of granulocyte colony stimulating factor mobilized peripheral blood stem cells versus marrow from HLA-compatible unrelated donors.

#### Blood and Marrow Clinical Trials Network (BMT CTN) Fludarabine-based Conditioning for Severe Aplastic Anemia (0301)

January 2006 - January 2016

Resources: Data only

BMT CTN 0301 was designed to determine the feasibility and toxicity of employing fludarabine-based conditioning to reduce transplant-related toxicity while maintaining (or ideally improving) engraftment in allogeneic donor marrow transplantation from matched and mismatched unrelated donors in patients with severe aplastic anemia.

Blood and Marrow Clinical Trials Network (BMT CTN) Multicenter Phase II, Double-blind Placebo Controlled Trial of Maintenance Ixazomib After Allogeneic Hematopoietic Stem Cell Transplantation for High Risk Multiple Myeloma (1302)

Clinical Trial

August 2015 - October 2020 Resources: Data only

The BMT CTN 1302 study was initiated to evaluate the efficacy of ixazomib maintenance therapy after reduced-intensity conditioning allogeneic stemcell transplantation from HLA-matched donors in patients with high-risk multiple myeloma.

#### Blood and Marrow Clinical Trials Network (BMT CTN) Optimizing Haploidentical Aplastic Anemia Transplantation (CHAMP 1502)

Clinical Trial June 2017- October 2021 Resources: Data only

The BMT CTN 1502 study was a prospective, multicenter phase II study with patients receiving haploidentical transplantation for severe aplastic anemia. The study resulted in excellent overall survival with minimal GVHD in patients who were refractory or relapsed after immunosuppressive therapy.

Blood and Marrow Clinical Trials Network (BMT CTN) Prospective Multi-Center Cohort for the Evaluation of Biomarkers Predicting Risk of Complications and Mortality Following Allogeneic HCT (1202)

Epidemiology Study June 2013 - September 2016

Resources: Data only

The BMT CTN 1202 study aimed to establish accurate and reproducible methods to diagnose, grade, and report graft-versus-host disease in patients post-hematopoietic cell transplantation.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) A Phase II/III Randomized, Multicenter Trial Comparing Sirolimus Plus Prednisone and Sirolimus/Calcineurin Inhibitor Plus Prednisone for the Treatment of Chronic Graft-versus-Host Disease (0801)

Clinical Trial

April 2010 - June 2018 Resources: Data only

BMT-CTN 0801 was a phase II/III trial designed to compare the responses of patients with graft-versus-host disease who received sirolimus/calcineurin inhibitor plus prednisone versus sirolimus plus prednisone.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) A Phase III Randomized, Multicenter Trial Testing Whether Exercise or Stress Management Improves Functional Status and Symptoms of Autologous and Allogeneic Recipients (0902)

Clinical Trial

January 2011 - November 2014

Resources: Data only

BMT CTN 0902 was designed to determine whether self-directed exercise and/or stress management improves self-reported physical and mental functioning compared to standard care in patients following autologous or allogeneic hematopoietic cell transplantation.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) A Randomized Double-Blind, Placebo-Controlled Trial of Soluble Tumor Necrosis Factor Receptor: Enbrel (Etanercept) for the Treatment of Acute Non-Infectious Pulmonary Dysfunction (Idiopathic Pneumonia Syndrome) Following Allogeneic Cell Transplantation (0403)

Clinical Trial

August 2007 to July 2013

Resources: Data only

BMT CTN 0403 was designed to determine the response and survival rate of patients with idiopathic pneumonia syndrome post allogeneic hematopoietic cell transplantation, following treatment with etanercept plus corticosteroids compared to placebo plus corticosteroids.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) A Randomized, Multi-Center, Phase III Study of Allogeneic Stem Cell Transplantation Comparing Regimen Intensity in Patients with Myelodysplastic Syndrome or Acute Myeloid Leukemia (0901)

Clinical Trial

May 2011 - January 2017 Resources: Data only

BMT CTN-0901 was a phase III randomized clinical trial designed to determine if reduced-intensity conditioning would result in improved overall survival given the lower treatment-related mortality compared with myeloablative conditioning in patients with myelodysplastic syndrome and acute myeloid leukemia.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) A Randomized, Multicenter, Phase III Trial of Tacrolimus/Methotrexate versus Post-Transplant Cyclophosphamide/Tacrolimus/Mycophenolate Mofetil in Non-Myeloablative/Reduced Intensity Conditioning Allogeneic Peripheral Blood Stem Cell Transplantation (1703)

Clinical Trial

June 2019 - September 2022

Resources: Data only

BMT CTN-1703 was a Phase 3 study comparing two graft-vs.-host-disease prophylaxis strategies in patients undergoing hematopoietic stem cell transplantation after reduced-intensity conditioning. This study was a follow up to BMT CTN-1203.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) A Trial of Single Autologous Transplant With or Without Consolidation Therapy Versus Tandem Autologous Transplant With Lenalidomide Maintenance for Patients With Multiple Myeloma (0702)

Clinical Trial

May 2010 - March 2018 Resources: Data only

The BMT CTN-0702 study was initiated to compare tandem autologous hematopoietic cell transplantation (AHCT) followed by lenalidomide maintenance, AHCT plus four cycles of lenalidomide, bortezomib, and dexamethasone (RVD) followed by lenalidomide, and AHCT and lenalidomide only in improving progression free survival for patients with active multiple myeloma.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Comparison of Fluconazole Versus Voriconazole to Treat Fungal Infections in Individuals Receiving Blood and Marrow Transplants (0101)

Clinical Trial 2003-2009

Resources: Data only

BMT CTN 0101 was designed as a Phase III study of fluconazole versus voriconazole for the prevention of fungal infections in allogeneic transplant recipients.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) High Dose Chemotherapy With Autologous Stem Cell Rescue for Aggressive B Cell Lymphoma and Hodgkin Lymphoma in HIV-infected Patients (0803)

Clinical Trial

April 2010 - June 2016 Resources: Data only

BMT CTN 0803 was designed to evaluate the effectiveness of autologous hematopoietic cell transplantation for HIV positive patients with chemotherapy-sensitive aggressive B cell lymphoma or Hodgkin's HIV-Related Lymphoma who received carmustine, etoposide, cytarabine, and melphalan (BEAM) as the pre-transplant conditioning regimen.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Multi-center, Open Label, Randomized Trial Comparing Single Versus Double Umbilical Cord Blood (UCB) Transplantation in Pediatric Patients With High Risk Leukemia and Myelodysplasia (0501)

Clinical Trial

December 2006 - October 2014

Resources: Data only

BMT CTN-0501 was designed to determine whether two partially HLA-matched umbilical cord-blood (UCB) units were better than one at improving one-year survival in pediatric patients with high risk leukemia or myelodysplasia.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Phase II Multicenter Trial of Single Autologous Hematopoietic Cell Transplant Followed by Lenalidomide Maintenance for Multiple Myeloma With or Without Vaccination With Dendritic Cell/Myeloma Fusions (1401)

Clinical Trial

July 2016 - December 2022 Resources: Data only

The BMT CTN-1401 study was initiated to compare response at one year post-transplant between participants receiving dendritic cell/myeloma vaccine along with granulocyte macrophage colony-stimulating factor (GM-CSF) and lenalidomide maintenance therapy to those receiving lenalidomide maintenance therapy with or without GM-CSF.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Phase II Randomized Trial Evaluating Etanercept, Mycophenolate Mofetil, Denileukin Diftitox, and Pentostatin in Co

Clinical Trial

September 2005 - June 2012 Resources: Data only

BMT CTN 0302 evaluated the effectiveness of each of four new drugs (etanercept, mycophenolate mofetil (MMF), denileukin diftitox (denileukin), and pentostatin) in combination with corticosteroids, as initial therapy for acute graft-versus-host disease.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Phase III Rituxan/BEAM vs. Bexxar/BEAM With Autologous Hematopoietic Stem Cell Transplantation (ASCT) for Persistent or Relapsed Chemotherapy Sensitive Diffuse Large B-cell Non-Hodgkin's Lymphoma (0401)

Clinical Trial

December 2005 - August 2013

Resources: Data only

BMT CTN 0401 compared progression-free survival after autologous hematopoietic stem cell transplantation for chemotherapy-sensitive diffuse large B-cell lymphoma using Rituxan/BEAM versus Bexxar/BEAM for pre-transplant conditioning.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Reduced Intensity Conditioning for Children and Adults With Hemophagocytic Syndromes or

Clinical Trial

November 2013 - December 2016

Resources: Data only

BMT CTN 1204 tested the safety and efficacy of intermediate timing (day -14) of alemtuzumab as part of a reduced-intensity conditioning protocol in subjects with hemophagocytic lymphohistiocytosis and other primary immunodeficiencies.

Blood and Marrow Transplant Clinical Trials Network (BMT CTN) Unrelated Donor Reduced Intensity Bone Marrow Transplant for Children With Severe Sickle Cell Disease (0601)

Clinical Trial August 2008-September 2016 Resources: Data only

BMT CTN 0601 was a phase II, single arm, multi-center trial designed to estimate the efficacy and toxicity of unrelated donor HCT using a reduced-intensity conditioning regimen in pediatric patients with Sickle Cell Disease and high-risk features.

#### Clarification of Optimal Anticoagulation Through Genetics (COAG)

Clinical Trial

September 2009 – November 2013

Resources: Data, DNA

COAG tested whether genotype-guided dosing of warfarin improves anticoagulation control during the first 4 weeks of therapy when compared to clinical-guided dosing.

#### **Cooperative Study of Sickle Cell Disease (CSSCD)**

**Epidemiology Study** 

1977-1995

Resources: Data, DNA, Serum

CSSCD examined the natural history of sickle cell disease from birth to death in order to identify factors contributing to the morbidity and mortality of the disease. Biospecimens from adult subjects who attended the 2A follow-up study are available for request. Phase 2A of the study examined the progression of organ damage in the heart, lung, kidney and liver in adult cohort patients enrolled in phase 1 of the study.

#### Cord Blood Transplantation Study (COBLT)

Epidemiology Study March 1999 - December 2003 Resources: Data only

COBLT investigated if banked unrelated donor umbilical cord blood could serve as an adequate hematopoietic stem cell source for adults and children with malignancies, immune deficiencies, inherited marrow failure, or inborn errors of metabolism.

#### Cure Sickle Cell Initiative (CureSCi) - Hematopoietic Cell Transplant for Sickle Cell Disease (HCT for SCD)

Epidemiology Study 1991 -

Resources: Data only

The overarching goals of the Center for International Blood and Marrow Transplant Research registry are to study trends in transplantations and to advance the understanding and application of allogeneic hematopoietic cell transplantation for malignant and non-malignant diseases.

#### Cure Sickle Cell Initiative (CureSCi) - Sickle Cell Hematopoietic Stem Cell Bank (SCBank)

Epidemiology Study

2021-2022

Resources: CD34+ Cells, CD34- Cells

The goal of the study is to generate a Sickle Cell Disease peripheral blood stem cell repository. Volunteer sickle cell disease patients were mobilized with plerixafor and peripheral blood stem cells were collected by apheresis.

#### Determination of the Optimal Prophylactic Platelet Dose Strategy to Prevent Bleeding in Thrombocytopenic Patients (PLADO)

July 2004-Janury 2008 Resources: Data only

PLADO was designed to evaluate the effect of prophylactic platelet transfusion dose on bleeding in patients with hypoproliferative thrombocytopenia.

#### Heparin-Induced Thrombocytopenia - Retrospective Analysis of Data on Incidence and Outcomes Study (HIT-RADIO)

Epidemiology Study June 2010-December 2010 Resources: Data only

HIT-RADIO was a retrospective analysis of positive heparin-PF4 antibody subjects to determine the time to occurrence of a composite triple endpoint of death, limb amputation/gangrene, and new thrombosis

## Hydroxyurea to Prevent Organ Damage in Children with Sickle Cell Anemia (BABY HUG) Phase III Clinical Trial and Follow-Up

Clinical Trial

August 2000 - September 2009 (Randomized Controlled Trial) August 2008 - December 2011 (Follow-Up Study I) January 2012 - December 2016 (Follow-Up Study II)

BABY HUG consists of a randomized controlled trial and two observational follow-up studies. The trial found that hydroxyurea can be considered safe and effective for all very young children with sickle cell anemia.

#### **Multicenter Hemophilia Cohort Studies (MHCS)**

Epidemiology Study MHCS-I: 1982-1996 ; MHCS-II: 2001-2005

Resources: Data, DNA, Peripheral Blood Mononuclear Cells, Plasma, Red Blood Cells, Serum

MHCS-I evaluated and prospectively followed patients with hemophilia or a related coagulation disorder in order to understand the cause and natural history of HIV infection and AIDS in this population which was at high risk for development of AIDS. MHCS-II evaluated and prospectively followed a cohort of subjects with hemophilia who were exposed to hepatitis C virus in order to quantify the rates of liver decompensation, hepatocellular carcinoma, and non-Hodgkin lymphoma, evaluate causal markers, identify predictive markers, identify genes that confer susceptibility or resistance, and identify response and complication rates of anti-HCV and anti-HIV treatment regimens.

#### **Multicenter Study of Hydroxyurea (MSH)**

Clinical Trial

1992-2008

Resources: Data, Buffy Coat, DNA, Serum

MSH evaluated whether or not treatment with hydroxyurea titrated to maximum tolerated doses would reduce the frequency of vaso-occlusive (painful) crises by at least 50%. This controlled trial made hydroxyurea the first drug of proven benefit in the prevention of vaso-occlusive pain crisis and acute chest syndrome caused by sickle cell disease.

#### NHLBI Umbilical Cord Blood Unit Collection (CBB)

**Epidemiology Study** 

1998-2001

Resources: Cord Blood Aliquot, Cord Blood Unit

CBB specimens were collected under the Cord Blood Transplantation Study Cord Blood Banking program with the objective of building an ethnically diverse unrelated cord blood bank and developing standard operating procedures for umbilical cord blood donor recruitment, selection and banking.

#### Natural History Study of Non-A, Non-B Post-Transfusion Hepatitis (NANB-TAH)

**Epidemiology Study** 1988 - 2001 Resources: Data, Serum

NANB-TAH was an extended follow-up study of 5 major prospective studies of transfusion-associated hepatitis that attempted to address the uncertainty about the frequency progression to clinically symptomatic and debilitating chronic liver disease and the frequency of fatal liver disease. The study, designed to track both mortality and morbidity of transfusion-associated non-A, non-B hepatitis, was a natural history evaluation that began at the time of disease onset and monitored subjects for almost 25 years.

#### Optimizing Primary Stroke Prevention in Children with Sickle Cell Anemia (STOP II)

Clinical Trial July 2000 - February 2006 Resources: Data only

STOP II evaluated whether prophylactic transfusion in patients with sickle cell disease and a high risk of stroke can be safely halted after 30 months of treatment during which patients became low risk for stroke.

#### Prospective Multi-Center Evaluation of the Duration of Therapy for Thrombosis in Children (Kids-DOTT)

Clinical Trial

March 2008 - February 2022 Resources: Data, DNA, Plasma, RNA

Kids-DOTT tested the hypothesis that a six-week duration of anticoagulant therapy for provoked venous thromboembolism is noninferior to a conventional three-month therapy duration in patients younger than 21 years of age.

#### Resuscitation Outcomes Consortium (ROC) Resources

ROC is a clinical trial network focusing on research in the area of prehospital cardiopulmonary arrest and severe traumatic injury.

#### Resuscitation Outcomes Consortium (ROC) Pragmatic Randomized Optimal Platelet and Plasma Ratios (PROPPR)

Clinical Trial

August 2012-December 2013

Resources: Data only

ROC-PROPPR assessed whether there is a reduction in massive transfusion complication and mortality rates by comparing subjects who received plasma, platelets, and red blood cells in a 1:1:2 ratio with those who received a more traditional transfusion ratio of 1:1:1.

#### Retrovirus Epidemiology Donor Study I (REDS I) Resources

The purpose of REDS I was to evaluate the human retroviruses HIV-1, HIV-2, HTLV-I and HTLV-II in blood donors from U.S. areas with varying risk for HIV. The study established blood specimen repositories for future testing.

#### Retrovirus Epidemiology Donor Study (REDS) Allogeneic Donor and Recipient Repository (RADAR)

**Epidemiology Study** 

2000-2003

Resources: Plasma, Serum, Whole Blood

REDS-RADAR is a linked donor-recipient collection whose purpose was to determine if newly identified or emerging pathogens can be transmitted by transfusion, and to build a more contemporary donor-recipient repository.

#### Retrovirus Epidemiology Donor Study (REDS) General Leukocyte/Plasma Repository (GLPR)

**Epidemiology Study** 

1994-1995

Resources: Plasma, Whole Blood

REDS-GLPR specimens were collected to provide researchers with a large representative sample of blood donors with linked demographic data and donation test results. Donor screening and testing included anti-HIV, anti-HCV, anti-HTLV, HBsAg and anti-HBc, serologic testing for syphilis and testing for ALT levels.

#### Retrovirus Epidemiology Donor Study (REDS) HTLV Cohort (HTLV)

Epidemiology Study 1989-2007

Resources: Data only

The purpose of REDS I was to evaluate the human retroviruses HIV-1, HIV-2, HTLV-I and HTLV-II in blood donors from U.S. areas with varying risk for HIV. The HTLV Cohort includes HTLV-I infected, HTLV-II infected and uninfected blood donors, all of whom were HIV type 1 seronegative at enrollment.

#### Retrovirus Epidemiology Donor Study II (REDS II) Resources

REDS II was a series of studies done with the objective of conducting epidemiological, laboratory and survey research on volunteer blood donors within the U.S. to ensure the safety and availability of the US blood supply.

#### Retrovirus Epidemiology Donor Study-II (REDS II) Donation and Deferral Database (CORE)

**Epidemiology Study** 2006 - 2009

Resources: Data only

REDS II-CORE aimed to build a well-developed blood donation database and deferral database to provide insight on critical issues within the blood banking community. The databases offer a look at the demographic characteristics of donors including racial/ethnic differences, donation patterns of first-time and repeat donors and deferral trends.

#### Retrovirus Epidemiology Donor Study-II (REDS II) Donor Iron Status Evaluation Study (RISE)

**Epidemiology Study** 2007-2009 Resources: Data only

REDS II-RISE was designed to evaluate the effects of blood donation intensity on iron and hemoglobin status, assess factors that could modify that relationship and provide data to help formulate optimal whole blood donation frequency.

#### Retrovirus Epidemiology Donor Study-II (REDS II) Leukocyte Antibodies Prevalence Study (LAPS)

Epidemiology Study 2006-2009

REDS II-LAPS was a two phase study. The LAPS-I study was designed to measure the prevalence of HLA and neutrophil antibodies in blood donors with or without a history of pregnancy or blood transfusion and to develop a repository of blood samples from well characterized blood donors whose detailed pregnancy and transfusion histories are known. The LAPS-II study was designed to evaluate a primary endpoint of combined incidence of transfusion-related acute lung injury (TRALI) and possible TRALI in study recipients of at least one HLA antibody-positive high-plasma-volume component received from a LAPS-I donor versus control recipients of at least one HLA antibody-negative high-plasma-volume component.

#### Retrovirus Epidemiology Donor Study-II (REDS II) Molecular Surveillance (MS)

**Epidemiology Study** 2006 - 2009 Resources: Data only

REDS II-MS conducted a genetic analysis of incident and prevalent strains of HIV, HCV and HBV by testing blood specimens from positive donors. Infected donors were identified among approximately 34 million U.S. blood donations based on screening and confirmatory tests for HIV and HCV nucleic acid testing, HIV and HCV antibody, HBsAg and anti-HBV core antibody.

## Retrovirus Epidemiology Donor Study-II (REDS II) Natural History of Disease and Laboratory Findings in Trypanosoma Cruzi Antibody-Positive Brazilian Blood Donors (Chagas)

**Epidemiology Study** 2008-2010 Resources: Data only

REDS II-Chagas was a retrospective cohort study meant to characterize the natural history of clinical Chagas disease, measure disease penetrance, and determine prognostic factors of Chagas cardiomyopathy among asymptomatic Trypanosoma cruzi-infected persons identified 10 years prior to the study.

#### Retrovirus Epidemiology Donor Study III (REDS III) Resources

REDS III established a research database infrastructure that links data from blood donors and their donations, the components made from these donations, and the recipients of these components.

#### Recipient Epidemiology and Donor Evaluation Study III (REDS III) U.S. Natural History Cohort of Zika Virus RNA Positive Blood Donors (U.S. Zika)

Epidemiology Study 6/24/2016-1/8/2018 Resources: Data only

The REDS-III US Zika Natural History Study sought to investigate the dynamics of viral and serological markers and clinical symptomatology following acute Zika virus infection in blood donors, and collect comprehensive data on viral persistence in blood compartments and body fluids in dengue virusexposed and -naïve donors

#### Recipient Epidemiology and Donor Evaluation Study III (REDS III) Vein to Vein Databases

**Epidemiology Study** 2012 - 2016 Resources: Data only

REDS-III aimed to ensure safe and effective blood banking and transfusion medicine practices through a comprehensive, multifaceted strategy involving basic, translational, and clinical research to improve the benefits of transfusion while reducing its risks.

#### Sickle Cell Disease Implementation Consortium (SCDIC) Sickle Cell Disease Patient Registry

Epidemiology Study

Resources: Data only

The SCDIC registry aimed to understand the barriers to care and other factors related to reduced healthcare utilization after the transition from pediatric to adult sickle cell disease care which may contribute to increased morbidity and mortality.

#### T-Cell Depletion in Unrelated Donor Marrow Transplantation (TCD)

Clinical Trial 1993-2005

Resources: Data only

TCD evaluated the impact of ex vivo T-Cell Depletion of marrow as compared with unmodified grafts on disease-free survival in recipients of unrelated donor bone marrow transplants

#### Transfusion Medicine and Hemostasis Clinical Trial Network (TMH CTN) Resources

The TMH CTN was established in 2002 in response to a demonstrated need for large multi-institutional clinical trials in transfusion medicine and

#### Transfusion Medicine and Hemostasis Clinical Trial Network (TMH CTN) - Red Cell Storage Duration Study (RECESS)

Clinical Trial

January 2010 - March 2014

The TMH-RECESS study was initiated to compare clinical outcomes after cardiac surgery in patients who received transfused red cells stored for 10 days or less or for 21 days or more.

#### Transfusion Medicine and Hemostasis Clinical Trial Network (TMH CTN) - Resolving Infection in Neutropenia With Granulocytes (RING)

Clinical Trial April 2008 - May 2013 Resources: Data only

The TMH-RING study was initiated to compare the safety and effectiveness of granulocyte transfusions along with standard care versus standard care alone in improving survival rates in people with a bacterial or fungal infection during neutropenia.

#### **Transfusion Safety Study (TSS)**

Epidemiology Study 1984 - 1997

Resources: Buffy Coat, Plasma, Plasma or Serum, Serum

TSS established two donor-recipient repositories consisting of a serum repository from donors in high AIDS prevalence areas in the U.S. and a plasma and cell repository from blood donors, transfusion and other blood product recipients and control cohorts. The repository has been used to evaluate factors influencing the risk of transfusion-transmitted HIV infection and its progression to clinically significant manifestations.

#### Transfusion of Prematures (TOP) Trial: Does a Liberal Red Blood Cell Transfusion Strategy Improve Neurologically-Intact Survival of Extremely-Low-Birth-Weight Infants as Compared to a Restrictive Strategy?

Clinical Trial December 2012 - February 2020

Resources: Data only

The TOP study investigated the effects of higher hemoglobin threshold transfusions on neurodevelopmental impairment in extremely-low-birth-weight infants.

#### Transfusion-Transmitted Viruses Study (TTVS)

**Epidemiology Study** 

1974-1980

Resources: Plasma or Serum, Serum

TTVS established a repository of specimens collected from prospectively identified cases of non-A, non-B (NANB) hepatitis after blood transfusion. The major intentions were to determine the incidence of that occurrence, identify the characteristics of the donors associated with the event and have a resource available to compare laboratory donor screening methods during the study and in subsequent years following completion of the study.

#### **Trial to Reduce Alloimmunization to Platelets (TRAP)**

Clinical Trial 1989-1997

Resources: Data only

TRAP examined whether the use of platelets from which leukocytes had been removed by a filter or that had been treated with ultraviolet B irradiation would prevent the formation of antiplatelet alloantibodies and refractoriness to platelet transfusions.

# <u>VA Cooperative Study of the Efficacy of Hepatitis Immune Serum Globulin for the Prevention or Modification of Post-Transfusion Hepatitis (VA2-TAH)</u>

Clinical Trial 1972 - 1976 Resources: Data, Serum

VA2-TAH was designed to test the efficacy of hepatitis B immune serum globulin for the prevention or modification of post-transfusion hepatitis as compared to immune serum globulin.

#### **Viral Activation Transfusion Study (VATS)**

Clinical Trial 1994-2001 Resources: Data only

VATS compared the effects of leukocyte-reduced and unmodified red blood cell transfusions on survival, complications of acquired immunodeficiency syndrome and relevant laboratory markers in HIV-infected patients.