



# BIOSPECIMEN and DATA RESOURCES

HIV / AIDS

# **NHBLI Biologic Specimen and Data Repositories**

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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) 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 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.

#### Longitudinal Studies of HIV-Associated Lung Infections and Complications (Lung HIV)

Epidemiology Study September 2007 – June 2012 Resources: Data only

Lung HIV was an initiative established to expedite the data and specimen collection results of eight different HIV and pulmonary studies operated under NHLBI. The project used these existing studies to create a foundation for future research and provide further insight on the relationship between pulmonary disease and HIV infection.

#### 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.

#### Pediatric Pulmonary and Cardiovascular Complications of Vertically Transmitted HIV Infection (P2C2)

Epidemiology Study May 1989 - March 2003 Resources: Data, Serum

P2C2 aimed to determine the prevalence and natural history of pulmonary and cardiac complications associated with HIV infection in utero, in infancy, and during early childhood.

#### Pulmonary Complications of HIV Infection Study (PACS)

Epidemiology Study 1987-1997 Resources: Data only

PACS evaluated the types, incidence, course, and outcome of pulmonary disorders in newly diagnosed cases of AIDS, newly diagnosed cases of AIDSrelated complex and newly diagnosed asymptomatic HIV infection.

**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) 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 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) 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.

# The Lung HIV Microbiome Project (LHMP)

#### Epidemiology Study October 2009 – November 2015 Resources: Bronchial Lavage, Oral Wash (Saline), Peripheral Blood Mononuclear Cells, Plasma

LHMP brought the distinct efforts of six clinical centers together under a single infrastructure, creating a collaborative network. The goals of the project were to characterize the microbiome of the lung and respiratory tract, and enhance understanding of the role of the lung microbiome in preserving health or causing disease and in the divergent effects observed in HIV-infected versus uninfected individuals.

# 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-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.

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.