



# BIOSPECIMEN and DATA RESOURCES

# **LUNG DISEASE**

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#### A Case Controlled Etiologic Study of Sarcoidosis (ACCESS)

Epidemiology Study June 1995 - March 2003

Resources: Data, Bronchial Lavage, DNA, Peripheral Blood Mononuclear Cells, Plasma

ACCESS examined the etiology of sarcoidosis, as well as socioeconomic variables and the clinical course of patients with sarcoidosis, including quality of

#### A Randomized Controlled Study of Adenotonsillectomy for Children with Obstructive Sleep Apnea Syndrome (CHAT)

Clinical Trial

October 2007 - June 2012 Resources: Data only

CHAT evaluated the efficacy of early adenotonsillectomy versus watchful waiting with supportive care, with respect to cognitive, behavioral, quality-oflife, and sleep factors in children with the obstructive sleep apnea syndrome.

#### Acute Respiratory Distress Network (ARDSNet) Resources

ARDSNet is a consortium of clinical centers and a coordinating center intended to design and test novel therapies for the treatment of Acute Lung Injury (ALI) and Acute Respiratory Distress Syndrome (ARDS).

Acute Respiratory Distress Network (ARDSNet) Studies 01 and 03 Lower versus higher tidal volume, ketoconazole treatment and lisofylline treatment (ARMA/KARMA/LARMA)

Clinical Trial 1996-1999

Resources: Data, Plasma, Serum, Urine

The Karma trial investigated the efficacy and safety of Ketoconazole and Respiratory Management in the treatment of ALI and ARDS. The ARMA component compared two ventilator strategies: a tidal volume of 6 mL/kg versus 12 mL/kg. The LARMA phase of the study investigated the efficacy of Lisofylline and Respiratory Management.

Acute Respiratory Distress Network (ARDSNet) Studies 06 and 08 Prospective, Randomized, Multicenter Trial of Aerosolized Albuterol Versus Placebo for the Treatment of Acute Lung Injury (ALTA)

Clinical Trial

August 2007 - November 2008

Resources: Data, Bronchial Lavage, DNA, Plasma, Urine

ARDSNet-ALTA tested the hypothesis that an aerosolized beta-2-agonist, albuterol, would improve clinical outcomes in patients with ALI and ARDS.

Acute Respiratory Distress Network (ARDSNet) Studies 07 and 08 Prospective, Randomized, Blinded, Placebo-controlled, Multi-center Trial of Omega-3 Fatty Acid, Gamma-Linolenic Acid, and Anti-Oxidant Supplementation in the Management of Acute Lung Injury or Acute Respiratory Distress Syndrome (Omega)

Clinical Trial 12/2007 - 04/2009

Resources: Data, Bronchial Lavage, DNA, Plasma, Urine

ARDSNet-Omega investigated if dietary supplementation of omega-3 (n-3) fatty acids, ?-linolenic acid and antioxidants to patients with ALI would increase ventilator-free days to study day 28.

Acute Respiratory Distress Network (ARDSNet) Studies 07, 08, 09, 11, and 12 Early Versus Delayed Enteral Feeding to Treat People with Acute Lung Injury or Acute Respiratory Distress Syndrome (EDEN)

Clinical Trial

12/2007 - 5/2011

Resources: Data, Bronchial Lavage, DNA, Plasma, Urine

ARDSNet-EDEN tested if initial lower-volume trophic enteral feeding would increase ventilator-free days and decrease gastrointestinal intolerances compared with initial full enteral feeding in ALI patients.

Acute Respiratory Distress Network (ARDSNet) Studies 10 and 12 Statins for Acutely Injured Lungs from Sepsis (SAILS)

Clinical Trial 2010 - 2013

Resources: Data, DNA, Plasma, Urine

ARDSNet-SAILS assessed the efficacy and safety of oral rosuvastatin in patients with sepsis-induced ALI and test the hypothesis that rosuvastatin therapy would improve the clinical outcomes of critically ill patients with sepsis-associated ARDS.

#### Acute Respiratory Distress Network (ARDSNet) Study 02 Late Steroid Rescue Study (LaSRS)

1997-2003

Resources: Data, BAL Slides, Bronchial Lavage, Plasma

ARDSNet-LASRS tested the effects of methylprednisolone, a corticosteroid, compared to placebo, on mortality at 60 days in patients with persistent ARDS.

#### Acute Respiratory Distress Network (ARDSNet) Study 04 Assessment of Low tidal Volume and elevated End-expiratory volume to Obviate Lung Injury (ALVEOLI)

Clinical Trial 1999-2002

Resources: Data, DNA, Plasma

ARDSNet-ALVEOLI compared clinical outcomes of patients with ALI and ARDS treated with a higher end-expiratory lung volume/lower FiO2 versus a lower end-expiratory lung volume/higher FiO2 ventilation strategy.

#### Acute Respiratory Distress Network (ARDSNet) Study 05 Fluid and Catheter Treatment Trial (FACTT)

Clinical Trial

2000-2005

Resources: Data, DNA, Plasma, Serum

ARDSNet-FACTT evaluated the benefits and risks of Pulmonary Artery Catheters (PACs) in patients with established ALI by comparing hemodynamic management guided by a PAC with hemodynamic management guided by a central venous catheter.

#### Asthma Clinical Research Network (ACRN) Resources

ACRN was initiated to perform multiple controlled clinical trials for treating patients with asthma.

#### Asthma Clinical Research Network (ACRN) Beta Adrenergic Response by Genotype (BARGE)

Clinical Trial 1993-2008

Resources: Data only

ACRN-BARGE examined the use of regularly scheduled albuterol treatment in asthma, in a genotype-stratified, randomized, placebo-controlled crossover trial in patients with mild asthma.

#### Asthma Clinical Research Network (ACRN) Beta Agonist in Mild Asthma Study (BAGS)

Clinical Trial 1994-1996

Resources: Data only

ACRN-BAGS tested the hypothesis that in patients with mild asthma, whose only asthma treatment is inhaled Beta-agonists, addition of regular inhaled Beta-agonist treatment to treatment on an "as needed only" basis will result in no effect on asthma control.

#### Asthma Clinical Research Network (ACRN) Colchicine In Moderate Asthma (CIMA)

Clinical Trial

February 1996 - June 1996 Resources: Data only

ACRN-CIMA tested the therapeutic benefit of colchicine as measured by maintenance of control when inhaled steroids are discontinued in patients with moderate asthma.

## Asthma Clinical Research Network (ACRN) Dose of Inhaled Corticosteroids with Equisystemic Effects (DICE)

Clinical Trial 1998-1999

Resources: Data only

ACRN-DICE aimed to establish a reliable method to evaluate systemic bioavailability and to determine equisystemic effects in inhaled corticosteroids.

## Asthma Clinical Research Network (ACRN) IMProving Asthma Control Trial (IMPACT)

Clinical Trial

May 2000 - May 2003 Resources: Data only

ACRN-IMPACT evaluated the efficacy of intermittent short-course corticosteroid treatment guided by a symptom-based action plan alone or in addition to daily treatment with either inhaled budesonide or oral zafirlukast over a one-year period.

#### Asthma Clinical Research Network (ACRN) Measuring Inhaled Corticosteroid Efficacy (MICE)

Clinical Trial 1999-2000

Resources: Data only

ACRN-MICE compared the relative beneficial and systemic effects in a dose-response relationship for two inhaled corticosteroids; beclomethasone dipropionate and fluticasone propiante.

#### Asthma Clinical Research Network (ACRN) Predicting Response to Inhaled Corticosteroid Efficacy (PRICE)

Clinical Trial

June 2003 - September 2004

Resources: Data only

ACRN-PRICE evaluated potential biomarkers of predicting short-term response to inhaled corticosteroid with subsequent evaluation of responders and non-responders to asthma control over a longer interval.

#### Asthma Clinical Research Network (ACRN) Salmeterol Off CorticoSteroids (SOCS) and Salmeterol Inhaled Corticosteroids (SLIC)

Clinical Trial 1997-1999

Resources: Data only

ACRN-SOCS and ACRN-SLIC were concurrently managed clinical trials that investigated whether inhaled corticosteroid therapy can be reduced or eliminated in patients with persistent asthma after adding a long-acting beta 2-agonist to their treatment regimen.

#### Asthma Clinical Research Network (ACRN) Salmeterol and Leukotriene Modifiers vs. Salmeterol and ICS Treatment (SLIMSIT)

Clinical Trial 2003-2004

Resources: Data only

ACRN-SLIMSIT evaluated the clinical efficacy of regular asthma treatment with the combination of a leukotriene receptor antagonist (montelukast) and a long-acting beta-agonist (salmeterol).

#### Asthma Clinical Research Network (ACRN) Smoking Modulates Outcomes of Glucocorticoid Therapy in Asthma (SMOG)

Clinical Trial 2002 - 2004

ACRN-SMOG evaluated if the response to an inhaled corticosteroid or a leukotriene receptor antagonist is attenuated in individuals with asthma who smoke.

# Asthma Clinical Research Network Trial (ACRN) - Best Adjustment Strategy for Asthma in Long Term (BASALT) and Tiotropium Bromide as an Alternative to Increased Inhaled Corticosteroid in Patients Inadequately Controlled on a Lower Dose of Inhaled Corticosteroid (TALC)

June 2007 - July 2010 (BASALT) | May 2008 - May 2010 (TALC)

Resources: Data only

ACRN-BASALT investigated if adjustment of inhaled corticosteroid therapy based on exhaled nitric oxide or day-to-day symptoms is superior to guideline-informed, physician assessment-based adjustment in preventing treatment failure in adults with mild to moderate asthma. ACRN-TALC examined the effectiveness of the medication tiotropium bromide combined with a low dose of inhaled corticosteroid at maintaining asthma control in people with moderately severe asthma.

#### Asthma Clinical Research Network Trial (ACRN) - Long-Acting Beta Agonist Response by Genotype (LARGE)

Clinical Trial

December 2004 - February 2008

Resources: Data only

ACRN-LARGE evaluated whether regularly scheduled use of an inhaled long-acting beta agonist (salmeterol) in the setting of concomitant use of inhaled corticosteroids would have a detrimental effect on asthma control in people who bear the B16 Arg/Arg genotype of the beta-2 adrenergic receptor gene.

# Asthma Clinical Research Network Trial (ACRN) - Macrolides in Asthma (MIA)

Clinical Trial July 2006 - March 2009

ACRN-MIA tested the hypothesis that clarithromycin would improve asthma control in individuals with mild-to-moderate persistent asthma that was not well-controlled despite treatment with low-dose inhaled corticosteroids.

#### **AsthmaNet Resources**

AsthmaNet is a nationwide clinical research network that developed and conducted multiple clinical trials that explore new approaches in treating asthma from childhood through adulthood.

#### AsthmaNet Airway Microbiome in Asthma: Relationships to Asthma Phenotype and Inhaled Corticosteroid Treatment

Clinical Trial Oct 2012 - July 2014

The MICROBIOME study aimed to compare the bronchial bacterial microbiota in adults with steroid-naive atopic asthma, with atopy but no asthma, and non-atopic healthy subjects; and to determine whether inhaled corticosteroid treatment alters bronchial microbial community composition in adults with asthma.

AsthmaNet Azithromycin for Preventing the Development of Upper Respiratory Tract Illness Into Lower Respiratory Tract Symptoms in Children (APRIL) and Oral

Clinical Trial

March 2011 - January 2015

Resources: Data, DNA, Plasma

The APRIL study evaluated the early administration of azithromycin in preschool children with recurrent severe lower respiratory tract illnesses and found that it reduced the likelihood of severe illness. The OCELOT study assessed the efficacy of oral corticosteroids in decreasing the severity of symptoms of children whose episode progressed to recurrent severe wheezing, but the trial was prematurely terminated due to a lack of feasibility.

#### AsthmaNet Best African American Response to Asthma Drugs (BARD)

Clinical Trial

February 2014 - July 2017 Resources: Data, DNA, Plasma, RNA, Sputum

The BARD trials evaluated whether patients of African American heritage with inadequately controlled asthma benefit from the addition of a longacting beta-agonist and/or increased glucocorticoids dosage in order to determine a preferred pharmacotherapy strategy in African American children, adolescents, and adults.

#### AsthmaNet Individualized Therapy For Asthma in Toddlers (INFANT) and Acetaminophen Versus Ibuprofen in Children With Asthma (AVICA)

February 2013 - April 2015

INFANT was designed to determine whether individual young children with mild persistent asthma responded better to one treatment than another and, if so, whether those children can be identified by phenotypic characteristics. AVICA compared the use of acetaminophen to the use of ibuprofen on asthma exacerbations among young children with mild persistent asthma.

#### AsthmaNet Proof of Concept Study of Alendronate for Asthma (ALFA)

Clinical Trial

January 2015 - September 2016 Resources: Data, DNA, Plasma

ALFA aimed to determine whether alendronate can reduce long-acting beta-2-adrenergic receptor agonist-associated loss of bronchoprotection in inhaled corticosteroid-treated patients.

# AsthmaNet Step-up Yellow Zone Inhaled Corticosteroids to Prevent Exacerbations (STICS)

Clinical Trial

July 2014-April 2017

Resources: Data, DNA, Plasma

AsthmaNet-STICS was a double-blind, parallel-group trial that assessed the efficacy and safety of increasing the dose of inhaled glucocorticoids by a factor of 5 for 7 days in school-age children with mild-to-moderate persistent asthma at the early signs of loss of asthma control.

#### AsthmaNet Steroids in Eosinophil Negative Asthma (SIENA)

Clinical Trial

July 2014 - May 2018 Resources: Data, DNA, Plasma, RNA, Sputum

SIENA was designed to compare an inhaled glucocorticoid with placebo and a long-acting muscarinic antagonist with placebo in patients with mild, persistent asthma, according to the patient's sputum eosinophil level at baseline.

#### AsthmaNet Vitamin D Add-on Therapy Enhances Corticosteroid Responsiveness in Asthma (VIDA)

Clinical Trial

April 2011 - January 2014

Resources: Data, DNA, Plasma, RNA, Sputum

VIDA was designed to evaluate if vitamin D supplementation would improve the clinical efficacy of inhaled corticosteroids in patients with symptomatic asthma and lower vitamin D levels.

#### **Broccoli Sprouts Extracts Trial (BEST-COPD)**

September 2010-July 2013 Resources: Data only

BEST-COPD aimed to establish a safe and tolerable dose of sulforaphane that effects in vivo antioxidants via Nrf2 for development as a potential novel treatment for patients with COPD.

#### Childhood Asthma Management Program (CAMP)

Clinical Trial

September 1991 - March 2012

CAMP evaluated whether continuous, long-term treatment with either an inhaled corticosteroid or an inhaled noncorticosteroid drug safely produces an improvement in lung growth as compared with treatment for symptoms only. The three continuation studies extended follow-up of the clinical trial cohort for an additional 4.5, 3.75, and 4 years respectively to observe asthma progression.

## Childhood Asthma Research and Education (CARE) Network Resources

The CARE Network was created to conduct multiple, well-designed clinical trials for rapid evaluation of new and existing therapeutic approaches to asthma and to disseminate laboratory and clinical findings to the health care community.

#### Childho (CLIC) od Asthma Research and Education (CARE) Network Characterizing the Response to a Leukotriene Receptor Antagonist and an Inhaled Corticosteroid

Clinical Trial

January 2002-March 2003 Resources: Data only

CARE-CLIC evaluated if response to inhaled corticosteroids and leukotriene receptor antagonists is similar in children with mild-to-moderate persistent asthma, or if children who do not respond to one medication respond to the other.

#### Childhood Asthma Research and Education (CARE) Network Trial - Acute Intervention Management Strategies (AIMS)

Clinical Trial February 2004-November 2006

Resources: Data only

The CARE-AIMS study compared the effectiveness of episodic use of an inhaled corticosteroid and a leukotriene receptor antagonist on reduction of morbidity in preschoolers with moderate-to-severe intermittent wheezing.

# Childhood Asthma Research and Education (CARE) Network Trial - Best Add-On Therapy Giving Effective Response (BADGER)

Clinical Trial

March 2007-December 2011 Resources: Data only

The CARE-BADGER study compared the effectiveness of a higher dose of inhaled corticosteroids (ICS), ICS combined with a long-acting beta-agonist medication, and ICS combined with a leukotriene receptor antagonist medication at reducing the impact and severity of asthma exacerbations that occur in children with mild to moderate persistent asthma.

#### Childhood Asthma Research and Education (CARE) Network Trial - Montelukast or Azithromycin for Reduction of Inhaled Corticosteroids in Childhood Asthma (MARS)

Clinical Trial

March 2006 - March 2007

Resources: Data only

The CARE-MARS study aimed to determine if azithromycin or montelukast use would allow reduction of inhaled corticosteroids in children with moderate to severe persistent asthma.

#### Childhood Asthma Research and Education (CARE) Network Trial - Pediatric Asthma Controller Trial (PACT)

August 2002 - September 2004

Resources: Data only

The CARE-PACT study was designed to determine whether, in children with mild to moderate persistent asthma, similar or greater asthma control could be obtained with a regimen of a LABA and half the dose of an ICS known to be effective compared to an ICS alone or a LTRA.

#### Childhood Asthma Research and Education (CARE) Network Trial - Prevention of Early Asthma in Kids (PEAK)

Clinical Trial

January 2001-September 2004

Resources: Data only

The CARE-PEAK study investigated whether inhaled corticosteroids modified the subsequent development of asthma in preschool children at high risk for asthma.

#### Childhood Asthma Research and Education (CARE) Network Trial - Treating children to Prevent Exacerbations of Asthma (TREXA)

Clinical Trial

November 2006 to December 2011

Resources: Data only

CARE TREXA assessed the effectiveness of inhaled corticosteroid (ICS) combinations for long term asthma control and exacerbations in pediatric patients.

#### Childhood Asthma Research and Education (CARE) Network Trial - Maintenance Versus Intermittent Inhaled Steroids in Wheezing Toddlers (MIST)

Clinical Trial

August 2008 - July 2010 Resources: Data only

The CARE-MIST study aimed to determine whether a daily low-dose regimen of budesonide would be superior to an intermittent high-dose regimen in preschool aged children who had positive values on the modified asthma predictive index along with recurrent wheezing.

#### Clinical Study of Intermittent Positive Pressure Breathing (IPPB)

Clinical Trial 1976-1983

Resources: Data only

IPPB evaluated the efficacy of long-term intermittent positive pressure breathing treatment when used as an adjunct to the overall care of ambulatory outpatients with chronic obstructive pulmonary disease as compared to use of a powered nebulizer.

# Colchicine Coronavirus SARS-CoV2 Trial (COLCORONA)

Clinical Trial

March 2020 - January 2021

Resources: Data only

The COLCORONA study aimed to investigate the effect of colchicine on the composite of COVID-19-related death or hospital admission in communitytreated patients.

# Effect of Positive Airway Pressure on Reducing Airway Reactivity in Patients With Asthma (CPAP)

July 2012 - October 2014 Resources: Data only

CPAP evaluated whether 12 weeks of nocturnal CPAP use would decrease the concentration of methacholine necessary to reduce FEV1 by 20% (PC20)

# Effectiveness and Safety of Intermittent Antimicrobial Therapy for the Treatment of New Onset Pseudomonas Aeruginosa Airway Infection in Young Patients with Cystic Fibrosis (EPIC)

Clinical Trial 2004-2009

Resources: Data only

EPIC investigated the efficacy and safety of four antipseudomonal treatments in children with cystic fibrosis with recently acquired Pseudomonas aeruginosa infection.

#### **High Frequency Ventilation in Premature Infants (HIFI)**

Clinical Trial 1984-1988 Resources: Data only

HIFI evaluated the hypothesis that high frequency oscillatory ventilation in preterm infants would reduce the incidence of mortality and pulmonary complications compared to conventional mechanical ventilation.

#### Idiopathic Pulmonary Fibrosis Network (IPFnet) Resources

IPFnet is a network of research centers dedicated to the study of idiopathic pulmonary fibrosis (IPF).

#### Idiopathic Pulmonary Fibrosis Network (IPFnet) AntiCoagulant Effectiveness in Idiopathic Pulmonary Fibrosis (ACE IPF)

Clinical Trial 10/2009 - 7/2011 Resources: Data only

IPFNet-ACE IPF hypothesized that treatment with warfarin at recognized therapeutic doses would reduce rates of mortality, hospitalization, and declines in Forced Vital Capacity in subjects with IPF.

# Idiopathic Pulmonary Fibrosis Network (IPFnet) Prednisone, Azathioprine, and N-Acetylcysteine: A Study That Evaluates Response in Idiopathic Pulmonary Fibrosis (PANTHER IPF)

Clinical Trial 10/2009 - 1/2014 Resources: Data only

IPFNet-PANTHER IPF evaluated the effectiveness of a drug combination of prednisone, azathioprine, and N-acetylcysteine in the treatment of mild-tomoderate IPF compared to N-acetylcysteine alone or placebo.

#### Idiopathic Pulmonary Fibrosis Network (IPFnet) Sildenafil Trial of Exercise Performance in Idiopathic Pulmonary Fibrosis (STEP IPF)

Clinical Trial 08/2007 - 10/2009 Resources: Data only

IPFNet-STEP IPF evaluated if treatment with sildenafil would improve walk distance, dyspnea, and quality of life in patients with advanced IPF.

## Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE)

Clinical Trial July 2015 - December 2016 Resources: Data only

The iCOMPARE trial aimed to compare all-cause mortality of patients cared for by trainees in internal-medicine residency programs with either standard duty hours or flexible duty hours. The Time and Motion substudy additionally aimed to determine the amount of time trainees spend on direct patient care and education. The Sleep and Alertness substudy aimed to determine the sleepiness of trainees.

## **Long-term Oxygen Treatment Trial (LOTT)**

Clinical Trial

January 2009- August 2015 Resources: Data only

LOTT evaluated the efficacy of long-term treatment with supplemental oxygen in patients with stable chronic obstructive pulmonary disease (COPD) and resting or exercise-induced moderate desaturation.

# 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.

#### Losartan Effects on Emphysema Progression (LEEP)

Clinical Trial

May 2017 - June 2021 Resources: Data only

The LEEP study was initiated to evaluate the efficacy of the angiotensin receptor blocker losartan on reducing the progression of emphysema in participants with COPD and mild to moderate emphysema.

#### **Lung Health Study (LHS)**

Clinical Trial 1984-2005

Resources: Data only

LHS examined the effects of Special Care, compared to Usual Care, on rate of decline in pulmonary function in cigarette smokers. Additionally, the study examined if participants with chronic obstructive pulmonary disease (COPD), who were assigned to inhaled corticosteroids had a lower rate of decline in lung function and lower incidence of respiratory morbidity. The study also evaluated the long-term effects of smoking cessation and continued smoking in subjects with early COPD.

#### **Lung Tissue Research Consortium (LTRC)**

Epidemiology Study March 2005 - February 2019

Resources: Data, DNA, Plasma, Serum, Tissue - FFPE Cassettes, Tissue - RNALater Frozen, Tissue - Snap Frozen

The LTRC was a biobank resource that collected lung tissue, blood samples, clinical data, and radiographic studies from participants with chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, other related idiopathic interstitial pneumonias and interstitial pneumonias associated with connective tissue diseases who undergo medically-indicated lung resection.

#### National Emphysema Treatment Trial (NETT)

Clinical Trial

1996-2005

Resources: Data only

NETT compared lung-volume-reduction surgery with medical therapy for severe emphysema, and identified patient selection criteria for lung volume reduction surgery. The current release of the NETT study dataset includes follow-up data through May of 2013.

#### New Data Analysis Methods for Actigraphy in Sleep Medicine (MASM)

Epidemiology Study July 2009 - November 2011 Resources: Data only

MASM measured activity data in subjects with sleep disorders or restless leg syndrome in order to define an object oriented data model for large activity datasets and patient level data, and apply existing and new advanced statistical and visualization methods for activity data.

# Novel Influenza A Surveillance Registry (H1N1)

Epidemiology Study October 2009 - October 2010

Resources: Data only

H1N1 aimed to characterize the demographics, clinical features, outcomes, and resource utilization of patients with H1N1 influenza infection who require intensive care.

## Patient Registry for Primary Pulmonary Hypertension (PPH Registry)

**Epidemiology Study** 

Resources: Data only

The PPH Registry evaluated the natural history, etiology, pathogenesis and treatment of primary pulmonary hypertension.

#### 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

#### Prematurity and Respiratory Outcomes Program (PROP) Core Database Protocol

Epidemiology Study August 2011 - March 2016 Resources: Data only

PROP aimed to identify suitable predictors of respiratory outcomes that may serve as surrogate endpoints in future trials of prevention and therapy of respiratory diseases in preterm infants.

#### Prevention and Early Treatment of Acute Lung Injury (PETAL) Resources

The PETAL Network was formed to develop and conduct randomized controlled clinical trials to prevent Acute Respiratory Distress Syndrome (ARDS) or provide early treatment to improve the outcome of patients who have ARDS.

#### Prevention and Early Treatment of Acute Lung Injury (PETAL) Acetaminophen in Sepsis: Targeted Therapy to Enhance Recovery (ASTER)

Clinical Trial 10/2021 - 7/2023 Resources: Data, Plasma, Urine, Whole Blood

The PETAL-ASTER study assessed the utility of plasma cell-free hemoglobin level as a biomarker for future sepsis trials and whether acetaminophen would increase the number of days alive and free of organ support for patients with sepsis and respiratory or circulatory organ dysfunction.

#### Prevention and Early Treatment of Acute Lung Injury (PETAL) Crystalloid Liberal or Vasopressors Early Resuscitation in Sepsis (CLOVERS)

Clinical Trial March 2018 - January 2023 Resources: Data, Plasma, Whole Blood

The PETAL-CLOVERS study compared the effects of a restrictive fluid strategy (with early use of vasopressors) to a liberal fluid strategy in patients with sepsis-induced hypotension.

# Prevention and Early Treatment of Acute Lung Injury (PETAL) Network - Low Tidal Volume Universal Support Feasibility of Recruitment for Interventional Trial (LOTUS FRUIT)

Epidemiology Study July 2016 - October 2016 Resources: Data only

PETAL-LOTUS FRUIT conducted a prospective, observational study of patients with acute respiratory failure to assess the feasibility for a cluster-randomized trial of low-tidal volume ventilation versus usual care in patients with acute respiratory failure.

# Prevention and Early Treatment of Acute Lung Injury (PETAL) Network - Outcomes Related to COVID-19 treated with Hydroxychloroguine among In-patients with symptomatic Disease (ORCHID)

Clinical Trial April 2020 - July 2020 Resources: Data only

The PETAL-ORCHID trial evaluated whether hydroxychloroquine is an efficacious treatment for adults hospitalized with COVID-19, with findings that did not support the use of this treatment.

# Prevention and Early Treatment of Acute Lung Injury (PETAL) Network - Repository of Electronic Data COVID-19 Observational Study (RED CORAL)

Epidemiology Study March 2020 - June 2020 Resources: Data only

The objective of PETAL-RED CORAL was to collect data for investigation of demographics, clinical characteristics, risk factors, care practices, outcomes and resource utilization of adult patients hospitalized with severe acute COVID-19.

# <u>Prevention and Early Treatment of Acute Lung Injury (PETAL) Network - Biology and Longitudinal Epidemiology of PETAL COVID-19 Observational Study (BLUE CORAL)</u>

Epidemiology Study June 2020 to March 2022

Resources: Data, Bronchial Lavage, Plasma, Tracheal Aspirate, Urine, Whole Blood

The BLUE CORAL study measured the incidence and changes over time in symptoms, disability, and financial status after COVID-19-related hospitalization to address the knowledge gaps and provide critical data to help guide clinical care, public health, and scientific efforts.

#### Prevention and Early Treatment of Acute Lung Injury (PETAL) Network - Functional, imaging, and respiratory evaluation in CORAL (FIRE CORAL)

Epidemiology Study June 2021 to May 2022 Resources: Data, Plasma, Whole Blood

The FIRE CORAL study examined the recovery from COVID-19 disease following acute hospitalization with an emphasis on functional, imaging, and respiratory evaluation, and assessed the feasibility of conducting a larger study to evaluate variables associated with differential recovery.

#### Prevention and Early Treatment of Acute Lung Injury (PETAL) Network - Reevaluation of Systemic Early Neuromuscular Blockade (ROSE)

Clinical Trial

January 2016 - April 2019

Resources: Data, DNA, Plasma, Urine, Whole Blood

The goal of PETAL-ROSE was to determine the efficacy and safety of early neuromuscular blockade with concomitant heavy sedation as compared with a strategy of usual care with lighter sedation targets in patients with moderate-to-severe ARDS.

#### Prevention and Early Treatment of Acute Lung Injury (PETAL) Network - Vitamin D to Improve Outcomes by Leveraging Early Treatment (VIOLET)

Clinical Trial

April 2017 - December 2018

Resources: Data, Plasma, Whole Blood

The PETAL-VIOLET study was initiated to evaluate the effect of short-term vitamin D supplementation on mortality among critically ill patients with a vitamin D deficiency.

#### Prospective Investigation of Pulmonary Embolism Diagnosis (PIOPED)

Clinical Trial 1983-1989

Resources: Data only

PIOPED examined the sensitivities and specificities of ventilation/perfusion lung scans for acute pulmonary embolism.

#### Proteomic Biomarkers of Survival in Idiopathic Pulmonary Fibrosis (IPF Survival Proteomics)

Epidemiology Study 2007 - 2021 Resources: Data only

The IPF Survival Proteomics study was initiated to identify and validate protein biomarkers associated with differential transplant-free survival in participants with idiopathic pulmonary fibrosis.

# Proteomic biomarkers of progressive fibrosing interstitial lung disease: a multicentre cohort analysis (PF-ILD Proteomics)

**Epidemiology Study** 2006 - 2021 Resources: Data only

PF-ILD Proteomics was initiated to identify novel plasma biomarkers of progressive fibrosing interstitial lung disease and develop a proteomic signature to predict this phenotype.

## 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 AIDS related complex and newly diagnosed asymptomatic HIV infection.

#### Randomized Evaluation of Sedation Titration for Respiratory Failure (RESTORE)

Clinical Trial January 2009 - December 2013 Resources: Data only

RESTORE evaluated whether critically ill children managed with a nurse-implemented, goal-directed sedation protocol would experience fewer days of mechanical ventilation than patients receiving usual care.

#### Randomized Order Safety Trial Evaluating Resident-physician Schedules Study (ROSTERS)

Clinical Trial July 2013 - March 2017 Resources: Data only

The ROSTERS study evaluated whether implementation of a schedule that eliminated shifts ≥24 hours for resident-physicians would result in improved patient safety.

#### Study of Asthma and Nasal Steroids (STAN)

Clinical Trial

September 2010 - June 2015 Resources: Data only

STAN tested whether treatment of chronic sinonasal disease with nasal corticosteroids improves asthma control in children and adults.

#### Study of Clinical Efficacy of Antimicrobial Therapy Strategy Using Pragmatic Design in Idiopathic Pulmonary Fibrosis (CleanUP IPF)

Clinical Trial

March 2017 - March 2020 Resources: Data only

CleanUP IPF investigated whether the addition of antimicrobial treatments improves outcomes compared to usual care alone among patients with idiopathic pulmonary fibrosis.

#### Subpopulations and Intermediate Markers in COPD Study (SPIROMICS)

Epidemiology Study November 2010 - July 2018

Resources: Data, Bronchial Lavage, Bronchial Wash, Oral Wash (Saline), Plasma, Serum, Sputum, Urine

SPIROMICS sought to identify homogeneous subgroups of chronic obstructive pulmonary disease patients for targeted enrollment in future therapeutic clinical trials, as well as to identify and conduct preliminary validation of intermediate biological or clinical outcomes for use as clinical trial endpoints.

#### 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.

## The Study of Soy Isoflavones in Asthma (SOYA)

Clinical Trial

March 2010 - August 2012 Resources: Data only

SOYA evaluated whether participants with poorly controlled asthma would have improved asthma control and lung capacity when prescribed a soy isoflavone supplement versus a placebo.

#### Trial of Late Surfactant for Prevention of Bronchopulmonary Dysplasia: A Study in Ventilated Preterm Infants Receiving Inhaled Nitric Oxide (TOLSURF)

Clinical Trial

January 2010-July 2015 Resources: Data only

TOLSURF assessed whether late surfactant treatment in extremely low gestational age newborn infants requiring ventilation at 7-14 days would safely improve survival without bronchopulmonary dysplasia.

## Trial of Roflumilast in Asthma Management (TRIM)

Clinical Trial

August 2018-July 2021 Resources: Data only

The TRIM study investigated the efficacy of roflumilast for the treatment of poorly controlled asthma in people with obesity. While roflumilast increased risk of asthma exacerbation, weight loss of at least 5% was associated with improved asthma control.

# Weighing Risks and Benefits of Laparoscopic Anti-Reflux Surgery in Patients With Idiopathic Pulmonary Fibrosis (WRAP-IPF)

Clinical Trial December 2013 - November 2017 Resources: Data only

WRAP-IPF was a multicenter randomized clinical trial designed to determine if the reduction of abnormal gastro-esophageal reflux with laparoscopic anti-reflux surgery will slow the progression of idiopathic pulmonary fibrosis as measured by forced vital capacity.