Materials for Panel 4:

Promoting Inter-IC Collaborations and Making the Most of Available Population Studies

Resources for information on ongoing population studies and availability of data and biomaterials in other NIH Institutes and Centers

Multi-IC Symposium on Application of Genomic Technologies to Population-Based Studies

June 5-6, 2006

NCI Consortia: http://epi.grants.cancer.gov/Consortia/cohort.html

National Cancer Institute
U.S. National Institutes of Health | www.cancer.gov

Epidemiology and Genetics Research
Cancer Control and Population Sciences

Cancer Control and Population Sciences Home

Epidemiology and Genetics Research

Areas of Research: Key Initiatives

Cohort and Case-control Consortia:

- Consortia Home
- Consortium of Cohorts
  - Mission Statement and Procedures
  - Membership
- Case-control Consortia

Related Consortium

- Breast and Prostate Cancer Cohort Consortium (BPC3)

Consortium of Cohorts

The Consortium of Cohorts was formed by NCI to address the need for large-scale collaborations for study of gene-gene and gene-environment interactions in the etiology of cancer, and more than 20 cohorts are participating.

In 2003, the Consortium launched its first initiative to pool data and biospecimens from 10 large cohorts, and is collaborating on studies of hormone-related gene variants and environmental factors involved in development of breast and prostate cancer. The cohorts in this study include nearly 800,000 research participants with available biospecimens.

Eight of the 10 participating cohorts are funded through EGRP:

- Physicians' Health Study I and II
- Nurses' Health Study
- Health Professionals Follow-up Study
- Women's Health Study
- American Cancer Society's Cancer Prevention Study - II (ACS CPS-II)
- European Prospective Investigation into Cancer and Nutrition (EPIC)
- Multiethnic Cohort

Two of the cohorts are part of the Division of Cancer Epidemiology and Genetics Research (DCEG), which is an intramural research arm of NCI:

- Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial
- Alpha-Tocopherol, Beta-carotene Cancer Prevention (ATBC) Study

In addition to studying gene-gene and gene-environment interactions, one of the goals of this research project is to show that pooling data and biospecimens across large-scale studies through consortia arrangements is an effective approach to conducting research on genes and the environment.

Contact Us

To discuss potential consortia arrangements, investigators may contact Edward Trapido, Sc.D., Associate Director of the Epidemiology and Genetics Research program (EGRP).
View information about existing EGRP-funded cohorts.
DCEG is a partner in this initiative.

NHLBI Population Studies Database: http://apps.nhlbi.nih.gov/popstudies/

Quick Search

Select Study Type

All

Select Disease or Condition of Interest

Select Age Group

All

Select Current Stage of Study

All

Submit Reset

Note: To take full advantage of this database, your browser must accept "cookies". By default, browsers accept them. If you or your system administrator has turned cookies off, you'll need to turn them back on. The cookies created are temporary and will be deleted at the end of your session.

Back to Scientific Resources

Welcome to the Population Studies Database of the National Heart, Lung, and Blood Institute (NHLBI). At this Web site you can find information regarding approximately 700 NHLBI-supported clinical trials and epidemiological studies.

Resource information for understanding clinical trials can be found on the NIH Clinical Trials Web Site. A compilation of internet sites related to cardiovascular epidemiology is available at the Web site of the University of California, San Francisco, Department of Epidemiology and Biostatistics.

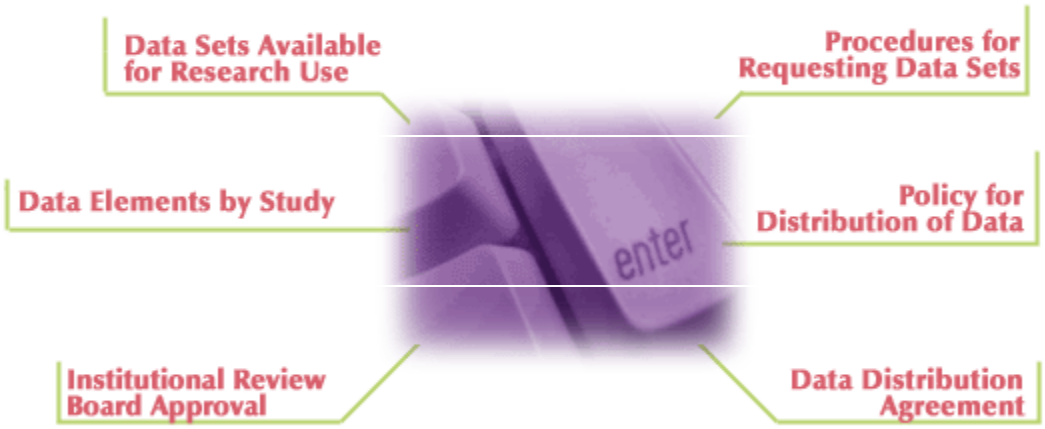
The data found at this site is regularly sent from the NHLBI to the NIH Clinical Trials Database. The NHLBI site has more narrative fields and fewer category fields than the NIH site. Otherwise, they contain the same data.

To view those studies or trials that are of interest to you, click on ***Quick Search*** above. Then click on the arrows on one or more of the four available windows: (1) the **Study Type**, (2) the **Disease or Condition** of interest, (3) the **Age of the Patient**, and/or (4) **Current Stage of the Study**. A drop-down list of choices will appear for each criterion. Scroll up and down and click on one or more of the choices in each window. To de-select a highlighted choice, click on it again.

If you would like to use additional criteria to search for trials and/or studies, click on the **Advanced Search** button.

If you have any questions or comments regarding this site, please send an e-mail to Dennis Askwith or call (301) 496-5031.

NHLBI Limited Access Data Sets:
http://www.nhlbi.nih.gov/resources/deca/default.htm



Please send us your feedback, comments, and questions
by using the appropriate link on the page, Contact the NHLBI.

Note to users of screen readers and other assistive technologies: please report your problems here.

NIDDK Ancillary Studies: http://www.niddk.nih.gov/fund/ancillary-studies/

Ancillary Studies to NIDDK and NHLBI Major Ongoing Clinical Research Studies

- Announcement Page
- PAR-04-078
- Descriptions of NIDDK Ongoing Clinical Research Studies Eligible for Ancillary Studies
- Descriptions of NHLBI Ongoing Clinical Research Studies Eligible for Ancillary Studies
- Policy Guidelines for NIDDK Ongoing Clinical Research Studies Eligible for Ancillary Studies

Last Updated: 3/10/2006

Acting Director: Dr. Griffin Rodgers || Contact NIDDK
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is part of the National Institutes of Health, Bethesda, MD, USA. General inquiries may be addressed to Office of Communications and Public Liaison, NIDDK, NIH, Building 31, room 9A04 Center Drive, MSC 2560, Bethesda, MD 20892-2560, USA.

NIA Database of Longitudinal Studies:
http://www.nia.nih.gov/ResearchInformation/ScientificResources/LongitudinalStudies.htm

Database of Longitudinal Studies

Introduction

In 2003, the National Institute on Aging (NIA) established the Longitudinal Data on Aging (LDA) working group to assist with the development of research initiatives for identifying the physiologic and other types of factors across the lifespan, affecting onset and progression of disease with advancing age, as well as elucidation of protective factors contributing to exceptionally healthy aging. This database was developed based on input from the LDA working group which indicated that establishing a database of existing sources of longitudinal data on aging (e.g., ongoing longitudinal cohorts, longitudinal data sets, biospecimen repositories) would be a valuable resource for facilitating future research on aging changes across the lifespan. The longitudinal studies, data sets and repositories included in this database encompass a wide range of age groups (childhood to old age), studies in minority populations, as well as sources of longitudinal data existing in the United States and abroad. Our primary purpose for establishing this database is to provide a resource for potential applicants for grants to the NIA. No part of this database can be used for commercial purposes.

Select a link below to start your search.

List of Current Studies Advanced Search

Searching the database

This online searchable database enables you to first select the gender, age-group of interest to you and to further refine your search using multiple keywords (i.e., Boolean AND/OR commands). The Boolean AND command is used in order to require that all search terms be present in this database. It can also be described as a Match All search. The Boolean OR command is used in order to allow any of the specified search terms to be present in this database. It can also be described as a Match Any search. Please refer to the links above for a list of keywords that were used to construct this database. We hope that you will find this searchable database to be user-friendly.

Acknowledgement

The NIA would like to thank the Canadian Institutes of Health Research, Division on Aging and Seniors, for granting us permission to use materials from the CIHR database of Longitudinal Studies on Aging in the development of the NIA database.

Send your comments or questions about this database to: gcgquery@nia.nih.gov.

Page last updated May 04, 2006

ClinicalTrials.gov description:
http://www.nlm.nih.gov/pubs/factsheets/clintrial.html

Fact Sheet ClinicalTrials.gov

Printer-friendly Version

What is *ClinicalTrials.gov*?
ClinicalTrials.gov provides patients, family members, health care professionals, and members of the public easy access to information on clinical trials for a wide range of diseases and conditions. The U.S. National Institutes of Health (NIH), through its National Library of Medicine (NLM), has developed this site in collaboration with all NIH Institutes and the Food and Drug Administration (FDA).

How do I find *ClinicalTrials.gov*?
ClinicalTrials.gov is available on the World Wide Web from the NLM Home Page (http://www.nlm.nih.gov/) or directly at *ClinicalTrials.gov* (http://clinicaltrials.gov/).
What information is in *ClinicalTrials.gov*?
Abstracts of Clinical Study Protocols that include the following information:

- summary of the purpose of the study
- recruiting status
- criteria for patient participation
- location of the trial and specific contact information

Additional Information that may help a patient decide whether to consider a particular trial:

- research study design
- phase of the trial
- disease or condition and drug or therapy under study

Links to Online Health Resources that help place clinical trials in the context of patients' overall medical care, including MEDLINE*plus* and PubMed.

Why has the National Institutes of Health (NIH) established *ClinicalTrials.gov*?
The *ClinicalTrials.gov* information resource was initiated as a result of the Food and Drug Administration Modernization Act of November 1997. The legislation requires the Department of Health and Human Services, through the NIH, to establish a registry of clinical trials for both federally and privately funded trials "of experimental treatments for serious or life-threatening diseases or conditions."

How are study protocols submitted to *ClinicalTrials.gov*?
The FDA Guidance Document (March 2002) (http://www.fda.gov/cder/guidance/4856fnl.htm) describes the submission criteria. The NLM has developed the Protocol Registration System (PRS), a Web-based tool for submitting information to *ClinicalTrials.gov*. Study sponsors or their representatives may register online to apply for a PRS account (http://prsinfo.clinicaltrials.gov/).

***ClinicalTrials.gov* facts**

- Completely confidential. No registration or personal identification is required.

• Includes thousands of trials sponsored by the U.S. NIH, government agencies, the pharmaceutical industry, and universities, foundations and other organizations from around the world.
• Released February 29, 2000.

Need more information?
NLM's toll-free number is 1-888-FINDNLM (1-888-346-3656)
NLM's e-mail address is custserv@nlm.nih.gov

A complete list of NLM Fact Sheets is available at:
(alphabetical list) http://www.nlm.nih.gov/pubs/factsheets/factsheets.html
(subject list): http://www.nlm.nih.gov/pubs/factsheets/factsubj.html

Or write to:

FACT SHEETS
Office of Communications and Public Liaison
National Library of Medicine
8600 Rockville Pike
Bethesda, Maryland 20894
Phone: (301) 496-6308
Fax: (301) 496-4450
email: publicinfo@nlm.nih.gov
Last updated: 15 December 2005
First published: 26 March 2003
Metadata| **Permanence level**: Permanent: Stable Content

Clinical Trials.gov search:
http://www.clinicaltrials.gov/ct/screen/AdvancedSearch

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Linking patients to medical research
Developed by the National Library of Medicine

Focused Search

Use this form to focus your search. Fill in any or all of the boxes below.
Click on the label to the left of each box for further explanation.

Search Tips

Disease or Condition:

Experimental Treatment:

Location: (Search for a specific facility or geographic location. Fill in any or all of the boxes below.)

Facility:
City:
State:
Country:

Additional Terms:

Age Group: ☐ Child (birth-17) ☐ Adult (18-65) ☐ Senior (66+)

Study Phase: ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV

Supported By: ☐ NIH ☐ Other Federal Agency ☐ Industry ☐ University/Organization

NCT or Study ID:

☐ Exclude synonyms from search

Search

Basic Search

Selected NIH Repositories

NIA Cell Repository: http://ccr.coriell.org/nia/

NIH Contact: Winifred Rossi, RossiW@mail.nih.gov

Description: Sponsored by the National Institute on Aging (NIA), the Aging Cell Repository, is a resource facilitating cellular and molecular research studies on the mechanisms of aging and the degenerative processes associated with it. The cells in this resource have been collected over the past three decades using strict diagnostic criteria and banked under the highest quality standards of cell culture. Scientists use the highly-characterized, viable, and contaminant-free cell cultures from this collection for research on such diseases as Alzheimer disease, progeria, Parkinsonism, Werner syndrome, and Cockayne syndrome.

Access: Cell cultures are distributed only to qualified professional persons who are associated with recognized research, medical, educational, or industrial organizations engaged in health-related research or health delivery. Before cell cultures or DNA samples can be shipped, the principal investigator must sign an Assurance Form detailing the terms and conditions of sale. This agreement must be renewed annually. In addition, before receiving lymphoblast or other virus-transformed cell cultures users should read the Minimum Safety Guidelines Recommended For Working With Human Cell Cultures. The form and guidelines are available electronically or may be obtained by contacting the Repository.

NIDA Center for Genetic Studies: http://zork.wustl.edu/nida/

NIH Contact: Jonathan Pollock, jpollock@nida.nih.gov

Description: The National Institute on Drug Abuse (NIDA) has established the Center for Genetic Studies, under a contract to Rutgers University and its subcontractor, Washington University, to produce, store, and distribute clinical data and biomaterials (DNA samples and cell lines) available in the NIDA Genetics Initiative.

Access: Researchers may gain access to clinical data, genetic analysis data, and biomaterials by obtaining formal approval from the NIDA Genetic Data Access Request Committee.

Additional information:

- Samples and cell lines from individuals diagnosed with substance abuse (22,000 samples to date) are available
- Samples and data can be submitted by all NIDA-funded investigators who agree to become members of the NIDA Genetics Consortium (NGC); services provided to NGC members free of charge
- The collected data and DNA samples are available for secondary data analysis by any qualified biomedical researchers at recognized biomedical research facilities.

NIDDK Central Repository: https://www.niddkrepository.org/niddk/home.do

NIH Contact: Rebekah Rasooly, rr185i@nih.gov

Description: On July 1, 2003, The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) established Central NIDDK Repositories for biosamples and data collected in clinical studies. The purpose of the Central Repositories is to expand the usefulness of these studies by providing access to the biosamples and data to a wider research community beyond the end of the study. There are three Central Repositories: Biosample Repository, Genetics Repository, and Data Repository.

Access: All qualified investigators will be allowed access to the stored materials at the end of a pre-determined proprietary period. The proprietary period for each study's materials will be mutually agreed upon by the study's Steering Committee and NIDDK. For multi-site clinical studies, NIDDK policy is that this proprietary period be no longer than 2 years from accrual of the last sample or patient data.

Researchers who want to access the materials and data stored in the Central Repositories will submit an application to the NIDDK. In order to receive samples or data, the institution will have to sign a Usage Agreement with NIDDK (http://pubnts06.rti.org/niddkdocs/forms/Draft%20Data%20Use%20Agreement%20for%20Repository.doc). The agreement will include certification the project has IRB approval, that the investigators will only conduct the research consistent with the subjects' informed consent, and that researchers will not attempt to identify any individuals. In addition, the Agreement will forbid any redistribution of the materials by the investigator or institution.

NIGMS Human Genetic Cell Repository: http://ccr.coriell.org/nigms/

NIH Contact: Richard Anderson, andersri@mail.nih.gov

Description: By providing the resources for human genome research, the Human Genetic Cell Repository, sponsored by the National Institute of General Medical Sciences (NIGMS), supplies scientists with the materials for accelerating disease gene discovery. The resources available include highly-characterized, viable, and contaminant-free cell cultures and high quality, well-characterized DNA samples derived from these cultures, both subjected to rigorous quality control.

Access: Cell cultures and DNA samples are distributed only to qualified professional persons who are associated with recognized research, medical, educational, or industrial organizations engaged in health-related research or health delivery. There are two requirements for ordering biomaterials from The NIGMS Human Genetic Cell Repository at Coriell:.

1. A Statement of Research Intent with a description of the research to be done with the cell cultures or DNA samples must be provided to the Repository. In the Statement of Research Intent there must be a declaration if there is to be secondary distribution or shared use of dna or Cell Cultures (see Human Policy or Animal Policy).
2. An Assurance Form (for Human or Animal samples) detailing the terms and conditions of sale must be signed by the principal investigator and the institutional official who can make legal commitments on behalf of the institution. Please note that from November 1, 1998 a single signature from an institutional official will be sufficient for all orders placed from that institution. Each of these presigned assurance forms also requires the signature of the Principal Investigator.

NIMH Human Genetics Initiative:
http://zork.wustl.edu/nimh/home/NIMH_Gen_Initiative.html

NIH Contact: Thomas Lehner, tlehner@mail.nih.gov

Description: The National Institute of Mental Health (NIMH) has established the Center for Collaborative Genetic Studies with a grant to Rutgers University and a sub-contract to Washington University, to produce, store, and distribute clinical data and biomaterials (DNA samples and cell lines) available in the NIMH Human Genetics Initiative. This Initiative is devoted to the collection and storage of family data for the genetic analysis of schizophrenia, bipolar I disorder, depression, Alzheimer's disease, autism, obsessive-compulsive disorder, and other mental disorders. These data and biomaterials are distributed to qualified investigators in the wider scientific community, for use in research on the genetic basis of these disorders.

Access: Researchers may gain access to clinical data, genetic analysis data, and biomaterials under one of two conditions: (1) a peer-reviewed NIMH research grant to analyze these data is awarded. In this circumstance, there is no charge to obtain DNA samples or lymphoblastoid cell lines; or (2) certification as a qualified investigator to access the data and biomaterials is obtained. In this circumstance, DNA samples or lymphoblastoid cell lines may be obtained from the NIMH Center for Genetic Studies after payment of all access fees as described in paragraph 10 of the Distribution Agreement.

NINDS Human Genetics Resource Center: http://ccr.coriell.org/ninds/

NIH Contact: Katrina Gwinn-Hardy, GwinnK@mail.nih.gov

Description: The NINDS Human Genetics Resource Center at the Coriell Institute is a bank for human cells, DNA samples, clinical data, and information sources. The goal of the Repository is the elucidation of genetic factors associated with neurological diseases. Genetic studies of neurological disorders are increasing in number and complexity. All samples must be collected with informed consent (under IRB approval) specifically indicating that the samples will become a part of the repository and that they will be maintained indefinitely.

Access: For those submitting samples, there is a grace period between sample submission to the repository and release by the repository of the sample publicly. Immediate sharing is encouraged: there is a maximum grace period of three years after the sample is submitted. Different fee schedules may apply for different grace periods, in order to encourage timely sharing of resources. All samples in the repository, which have completed the requisite grace period, will be available publicly. Those who have submitted samples will have access at markedly reduced costs. Samples which are publicly available can be found in the NINDS Repository Catalog. There is a nominal fee for submitting investigators to withdraw samples. For all other withdrawers, a fee scale exists which will vary depending on the affiliation of the withdrawer (academic institution versus industry user, NIH funded grantee versus other, sample series type to be withdrawn, etc).

Additional information:

- Cell lines and DNA for Parkinson's disease, stroke, epilepsy and motor neuron diseases, with control samples and accompanying clinical data are available
- Academic and industry-sponsored investigators may deposit or withdraw samples
- Over 2,500 samples are currently available

NHLBI Framingham Heart Study: http://www.nhlbi.nih.gov/about/framingham/index.html

NIH Contact: Paul Sorlie, sorliep@nhlbi.nih.gov

Description: The National Heart, Lung, and Blood Institute (NHLBI), in collaboration with Boston University, has supported collection of blood samples and clinical data from participants in the Framingham Heart Study since 1948. This clinically and genetically well-characterized population provides a rare and valuable scientific resource maintained under the joint stewardship of Boston University and the NHLBI.

Access: Although not a requirement, investigators interested in utilizing DNA and/or genetic data from the Framingham Study are encouraged to contact and work with Framingham investigators having similar or complementary interests since the data sets for this long-term study are quite complex. Applications for use of Framingham DNA or genetic data are accepted quarterly, on January 15, April 15, July 15, October 15 of each year. Investigators wishing to request DNA or genetic data will need to complete and submit:

1. Biologic Materials and Genetic Analysis Data Application and Proposal Form
2. Biographical Sketch
3. Supporting Documentation (as appropriate)

Prior to receipt of DNA or genetic data (but not required at the time of application), the requester will also need to submit:

4. Data and Materials Data and Materials Distribution Agreement
5. Human Subjects Approval from the Institutional Review Board (IRB) of the requester's institution is required prior to receipt of DNA or genetic data.

PHARMACOGENETICS RESEARCH NETWORK

www.nigms.nih.gov/pharmacogenetics
www.pharmgkb.org

The Pharmacogenetics Research Network is a trans-NIH effort, which was first funded in 2000. It is currently in its second five year renewal period, with support from **NIGMS** (leading the initiative), **NHLBI** (major contributing funder), **NIDA**, **NCI**, **NIMH**, **NHGRI**, **NIEHS**, **NLM**, and **ORWH**. The current total costs per year are approximately $28M for 12 awards.

The PGRN was conceived as a broad network-based approach to research studies in pharmacogenetics/pharmacogenomics, with the central feature of a database (PharmGKB) that would be hypothesis-generating and open to all scientific investigators. The original RFAs and subsequent renewal RFA stated that each group should be multidisciplinary (*e.g.,* with expertise in pharmacology, genetics, genomics, medicine, statistics, etc.) and should specify its own area of interest and its own approaches. Hence, there are **"genotype-to-phenotype"** groups focused on variant discovery in genes of known interest (cytochrome P450s, conjugating enzymes, transporters, adrenergic receptors, serotonergic receptors), with subsequent studies to determine functional and clinical significance, as well as **"phenotype-to-genotype"** groups focused of patient populations that display variable responses to treatment, with studies to determine the genetic/genomic contributions. In general, the initial approaches were based upon candidate genes, which expanded to become pathways of candidate genes, and in some cases whole genome association studies are now planned. In selected groups, unbiased gene discovery efforts are underway in model systems (*e.g.,* CEPH cell lines, or zebrafish). The range of drugs/diseases being studied is great, including drugs used to treat cardiovascular disease such as cholesterol-lowering drugs, anti-arrhythmics, anti-coagulants, and antihypertensives; drugs used for selected cancers including colorectal and breast cancers, and childhood leukemias; neuropsychiatric medications including antidepressants and nicotine cessation treatments; and asthma treatments via steroids, adrenergic agents, and leukotriene drugs. Investigators quickly discovered that despite studying different drug/ disease combinations, they had common interests in study approaches and mechanisms, *e.g.,* pathways of inflammation.

The PharmGKB was developed to share high value data sets from studies, to permit crucial mechanistic and statistical correlations to be made, and to represent the knowledge in a field. Information is organized at PharmGKB by genes, drugs, diseases, and pathways. Within those areas, phenotypes are categorized as molecular and functional assays, pharmacokinetic data, pharmacodynamic information, and clinical outcomes. These phenotypes are correlated with genotypes displayed on browsers, with information on haplotypes available, all fully linked to standardized archival databases (*e.g.,* dbSNP). PharmGKB is still growing, and the PGRN-funded investigators are charged with advising and developing its utility. There have always been ongoing discussions, including study groups and occasional supplements available, to address the ethical ramifications of research and data-sharing in the area of pharmacogenetics. This area, along with economics, will have an independent PA developed in Summer 2006.

The PGRN was charged with accomplishing more as a network than it could with equivalently funded individual awards. It had to develop policies that investigators agreed to in the areas of informed consent (model language is posted at PharmGKB, and is undergoing revision), intellectual property (the proposed approach is based upon provisional patents and no hinderance of research studies), timely deposition of data (upon completion of experiments and analysis, which was judged to be concurrent with acceptance of publication of a manuscript), and communications and interactions with the field in general. The PGRN is in the process of writing a series of "white papers" on challenges in the field, applications of pharmacogenetic testing, approaches to study adverse drug reactions, and educational efforts needed in the field. The PGRN also holds internal analysis workshops and periodic meetings focused in scientific areas such as the state of technology (*e.g.,* platforms, customized vs. stock, etc.) and sample banking efforts underway at leading academic research institutions. Anyone can apply to "join" the PGRN and attend the scientific meetings through the affiliate membership program.

PGRN MISSION STATEMENT:

Mission

The mission of the NIH PGRN is to advance our knowledge of the genetic basis for variable drug responses.

Background

The NIH Pharmacogenetics Research Network (PGRN) was formed in 2000 to enable a network of multi-disciplinary research groups to conduct studies addressing research questions in pharmacogenetics and pharmacogenomics (the genetic basis for variation in drug responses) and to populate a knowledge base (PharmGKB). The latter will be used as a research tool to enable future pharmacogenetics studies and should serve as the premier knowledge base in the field. In 2005, the PGRN was renewed for a second 5-year period. The PGRN has been led by NIGMS, with important participation from other NIH Institutes and Offices, including NHLBI, NIDA, NCI, NIEHS, NHGRI, NIMH, NLM and ORWH. Ultimately, the long term goal is to translate this knowledge and identify safe and effective drug therapies designed for individual patients.

Organization

The PGRN comprises 12 independently-funded interactive research groups, including the knowledge base group. Each research group has a focus in an identified area of pharmacogenetics (see members page for a full description of the PGRN research groups and their specific interests). The PGRN is accomplishing its mission by conducting studies of variation in human genes relevant to pharmacokinetics (drug disposition) and pharmacodynamics (drug action), and the relationship of such variation to drug response phenotypes, with deposition of the resulting data into the knowledge base, PharmGKB. PharmGKB contains both raw and curated information. It presents data and information accumulated in the field and contributed by researchers both within and beyond the network.

Goals

All PGRN groups are expected to advance pharmacogenetics research knowledge in their respective areas of focus. The work of the groups ranges from basic research into identifying variation in genes (and functional consequences) relevant to pharmacogenetics, to clinical research aimed at understanding the genetic basis for variable drug responses, both therapeutic and adverse. The aims of the PGRN include:

- Performing the **highest quality research studies** to understand and explain the relationships between drug response phenotypes and genetic variation, using state-of-the-art experimental approaches and technologies.
- Building a premier **web-based knowledge base** (PharmGKB) that rapidly disseminates accurate and detailed definitions of genotypes and phenotypes in pharmacogenetics, along with tools and resources.
- **Stimulating collaborations** within and beyond the PGRN through having a critical mass of researchers in cross-cutting areas.
- Interacting with and **influencing the wider community of scientists** in academia, industry, and government regulatory agencies, to advance the field.

Approved in 2005 by the PGRN and NIH

The PGRN has a committee of external advisors, the External Scientific Panel (ESP), which provides advice and guidance directly to the network on an annual basis. The ESP membership is posted at the PGRN web page. Annual reports are made to NIGMS Council.

The PGRN includes ~200 investigators at ~40 different sites in the US and Canada. The PGRN groups and their lead principal investigators are:

Russ B. Altman, MD, PhD Stanford University	Pharmacogenetics and Pharmacogenomics Knowledge Base Designing a knowledge base to link phenotypes to genotypes in pharmacogenetics and pharmacogenomics, to be used as a tool to enable future research efforts
Neal L. Benowitz, MD Univ. of California, San Francisco	Pharmacogenetics of Nicotine Addiction and Treatment Investigating the genetic basis of nicotine addiction and influences on responses to drug therapies used for smoking cessation
David A. Flockhart, MD, PhD Indiana University	Consortium on Breast Cancer Pharmacogenomics Describing normal functions of estrogen, and how genetic variation contributes to efficacy and toxicity of endocrine treatments for breast cancer
Kathleen M. Giacomini, PhD Univ. of California, San Francisco	Pharmacogenetics of Membrane Transporters Studying membrane transporter genes in ethnically diverse samples, determining cellular phenotypes, and correlating variants with the clinical response to antidepressants
Julie A. Johnson, PharmD University of Florida	Pharmacogenomic Evaluation of Antihypertensive Responses Identifying gene variants involved in responses to drugs commonly used for hypertension, a beta-blocker and a thiazide diuretic, to predict therapeutic and adverse responses
Ronald M. Krauss, MD Children's Hospital Oakland Research Institute	Pharmacogenetics Network for Cardiovascular Risk Therapy Defining genetic contributions to differences among individuals in their responses to statin drugs and cardiovascular disease risk
Howard L. McLeod, PharmD Washington University	Functional Polymorphism Analysis in Drug Pathways Identifying pathways of anti-cancer drugs, and taking novel approaches to pathway dissection, and functionally assessing variants
Mark Ratain, MD University of Chicago **Mary Relling, PharmD** St. Jude Children's Research Hosp.	Pharmacogenetics of Anticancer Agents Elucidating the impact of germ-line variants on the efficacy and adverse effects of anticancer drugs used to treat colorectal cancer and childhood leukemias
Dan M. Roden, MD Vanderbilt University	Pharmacogenomics of Arrhythmia Therapy Examining genes that modulate cardiac rhythm, accruing patients with QT responses to therapy, and evaluating drug responses in atrial fibrillation
Alan R. Shuldiner, MD University of Maryland	Amish Pharmacogenomics of Anti-Platelet Intervention Study Understanding genetic determinants of responses that vary among people taking anti-platelet agents used to treat and prevent cardiovascular disease
Richard Weinshilboum, MD Mayo Clinic	Pharmacogenetics of Phase II Drug Metabolizing Enzymes Discovering variants and identifying mechanisms involved in phase II conjugating enzymes controlling biotransformation of drugs, hormones, and neurotransmitters
Scott Weiss, MD Brigham and Women's Hospital	Pharmacogenetics of Asthma Treatment Using genetics to predict responders to asthma therapy, based upon understanding of asthma pathways and clinically significant variation