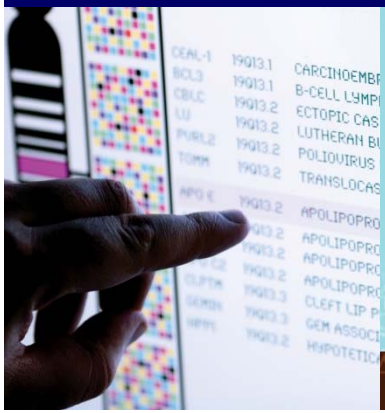
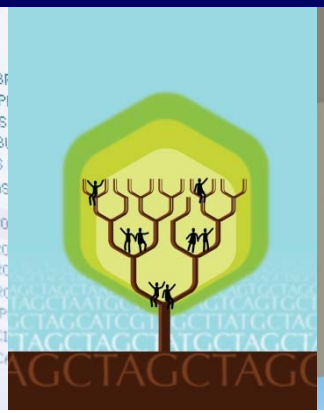
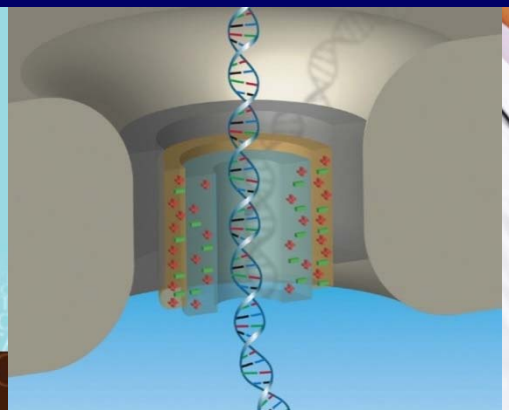
DIRECTOR'S REPORT

National Advisory Council for Human Genome Research

February 2017

Eric Green, M.D., Ph.D.
Director, NHGRI

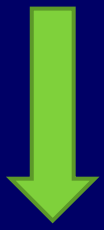
Director's Report-Related Documents: February 2017

Director's Report 

Director's Report 

No.	Relevant Documents
1	20th Anniversary of Institute Status
2	Francis Collins "Held Over" as NIH Director
3	New Chief Executive Officer, NIH Clinical Center
4	Kathy Hudson Departs as NIH Associate Director for Science, Outreach, and Policy
5	Phil Bourne Departs as NIH Associate Director for Data Science
6	21st Century Cures Act
7	Common Rule Revisions Finalized

genome.gov/DirectorsReport



Document #

Open Session Presentations

- **NIH Data Commons**
  Vivien Bonazzi

- **NHGRI Data Sandbox**
  Valentina Di Francesco

- **Genomics and Society Working Group**
  Lisa Parker

- **Building Bonds between NHGRI and NICHD**
  Diana Bianchi

Director's Report Outline

I. General NHGRI Updates

II. General NIH Updates

III. General Genomics Updates

IV. NHGRI Extramural Research Program

V. NIH Common Fund/Trans-NIH

VI. NHGRI Division of Policy, Communications, and Education

VII. NHGRI Intramural Research Program

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20th Anniversary of Institute Status

Document 1

Transition of NHGRI Chief Information Officer

Ed Whitley

New NHGRI Chief Information Officer

Joe Henke

Retirement of Clinical Advisor, Division of Policy, Communications, and Education

Jean Jenkins, PhD, RN, FAAN

Workshop on the Use of Race and Ethnicity in Genomics and Biomedical Research

- Co-sponsored by NHGRI and NIMHD
- Examined the complex relationships between individual identity, genetics, and health

Community Engagement Working Group


















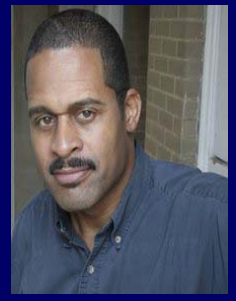

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Francis Collins “Held Over” as NIH Director

Francis Collins, M.D., Ph.D.

Document 2

2017 Congressional Leadership

NIH Oversight Committees

Greg Walden (OR)

Michael Burgess (TX)

	House	Senate
Appropriation	**Labor, HHS, & Education** Chairman Tom Cole (OK) Ranking Rosa DeLauro (CT)	**Labor, HHS, & Education** Chairman Roy Blunt (MO) Ranking Patty Murray (WA)
Authorization	**Energy & Commerce** Chairman Greg Walden (OR) Ranking Frank Pallone (NJ) *Health Subcommittee* Chairman Michael Burgess (TX) Ranking Gene Green (TX)	**Health, Education, Labor, and Pensions (HELP)** Chairman Lamar Alexander (TN) Ranking Patty Murray (WA)

New Chief Executive Officer, NIH Clinical Center

National Institutes of Health
Clinical Center

Major General James Gilman, M.D.

Document 3

Kathy Hudson Departs as NIH Associate Director for Science, Outreach, and Policy

Kathy Hudson, Ph.D.

Document 4

Phil Bourne Departs as NIH Associate Director for Data Science

Philip Bourne, Ph.D.

Document 5

21st Century Cures Act

The 21st Century Cures Act — A View from the NIH

Kathy L. Hudson, Ph.D., and Francis S. Collins, M.D., Ph.D.

- **$4.8 billion for NIH innovation projects**
- **Data sharing can be required**
- **Protection of identifiable and sensitive information: FOIA exemption**
- **Privacy protection for human research subjects: Certificates of Confidentiality**

Document 6

NIH Appropriations and Budget

	FY2016 Enacted	FY2017
NIH	$32.3 B	CR through April 28, 2017
NHGRI	$513.2 M	CR through April 28, 2017

SBIR/STTR Reauthorization

SBIR · STTR
America's Seed Fund™
POWERED BY SBA

Common Rule Revisions Finalized

- Improve informed consent
- Calibrate review to study risks
- Allow broad consent for secondary use of biospecimens
- Does not require consent for the use of de-identified biospecimens
- Streamline IRB review

FEDERAL REGISTER

Vol. 82 Thursday,
No. 12 January 19, 2017

ACTION: Final rule.

SUMMARY: The departments and agencies listed in this document announce revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was originally promulgated as a Common Rule in 1991. This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. These revisions are an effort to modernize, simplify, and enhance the current system of oversight.

DATES: This rule is effective on January 19, 2018. The compliance date for this rule, except for § ____.114(b) (cooperative research), is January 19, 2018. The compliance date for § ____.114(b) (cooperative research) is January 20, 2020.

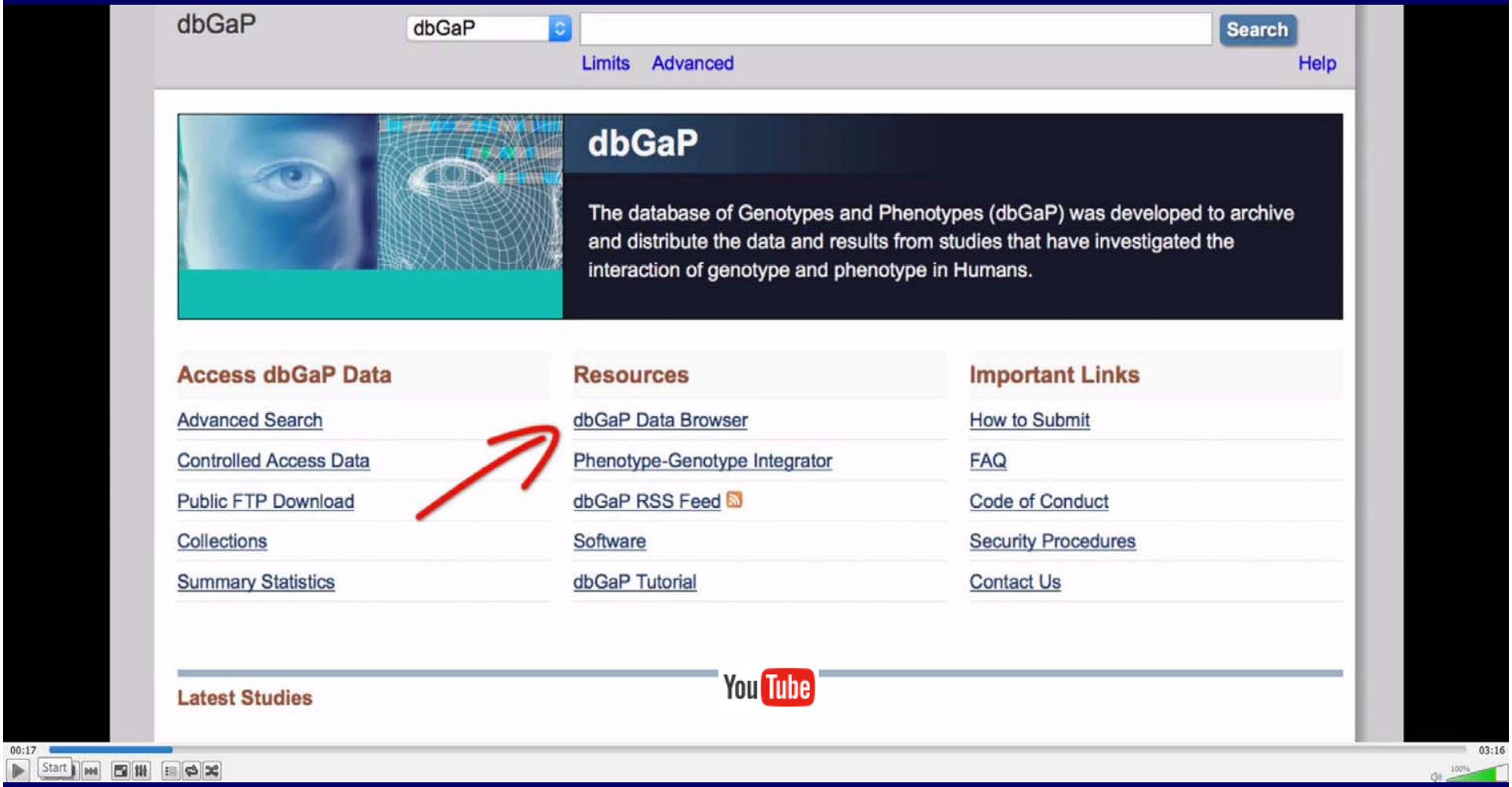
Document 7

Regulatory Updates

- FDA's Laboratory Developed Test (LDT) guidance delayed
- NIH Single-IRB Policy: Effective date extended to Sept. 25, 2017

Document 8

New dbGaP Data Browser

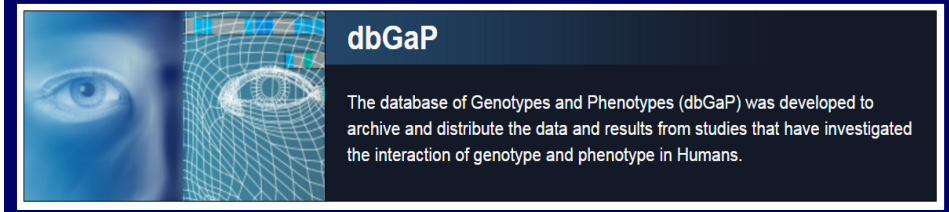


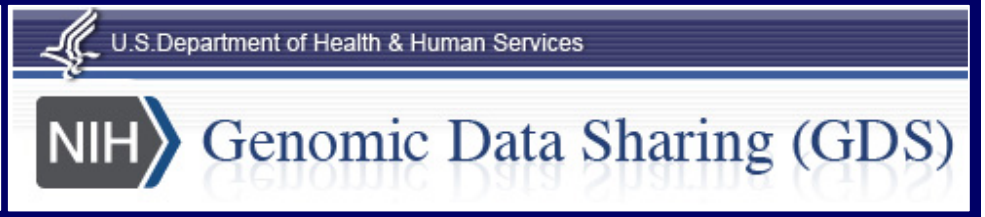
NCBI

NIH National Human Genome Research Institute

Document 9

RFI on dbGaP Streamlining





- **Will solicit feedback on data-submission and data-access processes**
- **Also will include policy-related questions:**
  - **Alternate controlled-access models**
  - **Benefits and risks associated with sharing genomic summary statistics**
  - **Use of genomic research data held in dbGaP for clinical reference purposes**

Document 10

NIH-ACMG Fellowship in Genomic Medicine Program Management

NIH National Institutes of Health

ACMG
American College of Medical Genetics and Genomics
Translating Genes into Health®

- Goal to increase the pool of physicians trained in managing research and implementation programs in genomic medicine
- Applications due March 1, 2017
- Fellowship begins July 2017

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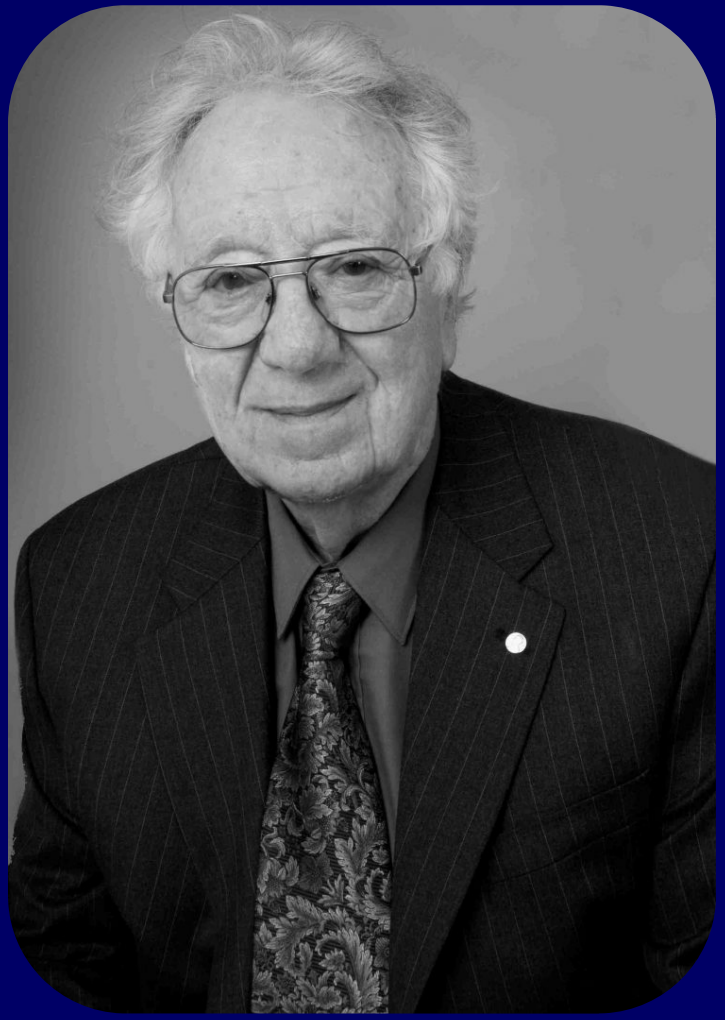
Mourning the Loss of Oliver Smithies

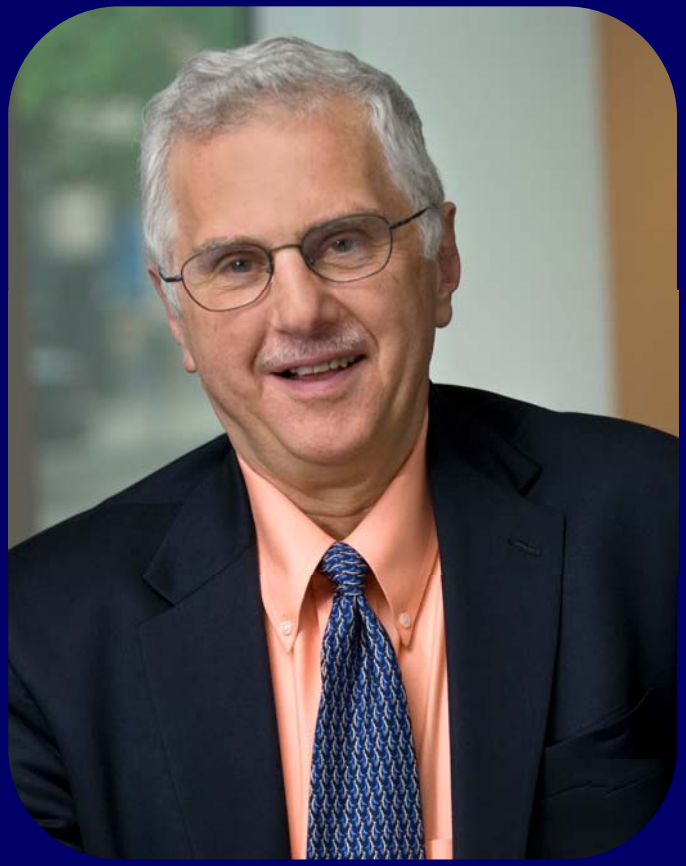


Document 12

Mourning the Loss of Allen Roses

Document 13

Lasker~Koshland Special Achievement Award in Medical Science



Bruce Alberts, Ph.D.

Document 14

2017 Breakthrough Prize in Life Sciences

LIFE SCIENCES
BREAKTHROUGH
PRIZE

Huda Zoghbi, M.D.

2016 ASHG Awards

Brendan Lee,
M.D., Ph.D.

David Valle,
M.D.

ASHG2016
VANCOUVER • OCTOBER 18-22, 2016
SHARING DISCOVERIES. SHAPING OUR FUTURE.

Document 16

New Steering Committee Chair, Global Alliance for Genomics and Health

Ewan Birney, Ph.D.

Global Alliance for Genomics & Health

New Senior Vice President of Global Oncology, Lilly

Lilly

Levi Garroway, M.D., Ph.D.

Document 18

Elected to the National Academy of Medicine

Anita Allen

Leslie Biesecker

Rob Califf

Joseph DeRisi

Allison Goate

Mark Musen

Kenneth Offit

Craig Venter

Huntington Willard

Xiaoliang Sunney Xie

David Walt

Document 19

Elected to the AAAS

Paul Aristoff
Stephen Fodor
Monica Justice
Craig Lindsley
Clifton Poodry
Gary Stormo
Sharlene Weatherwax

Document 20

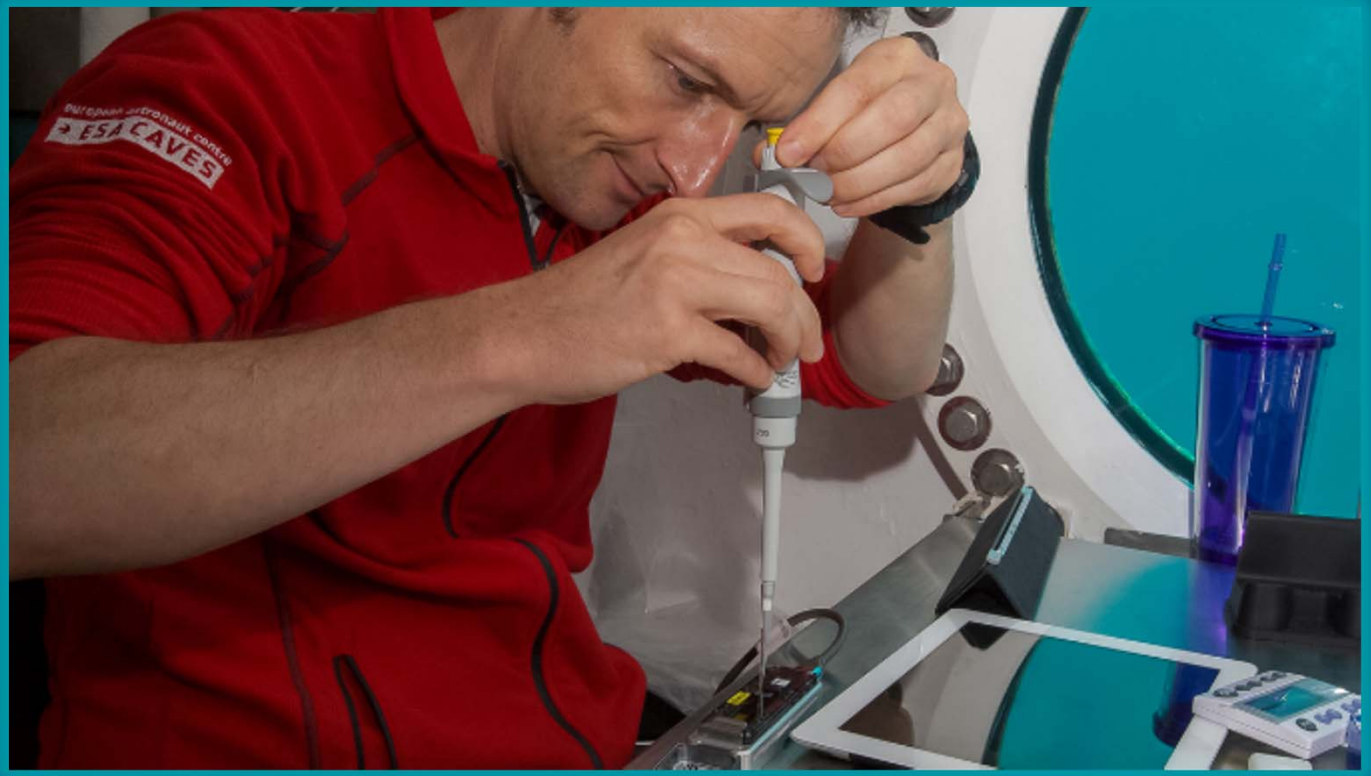
2016 SBIR Hall of Fame and Tibbetts Award

illumina®

23andMe

Document 21

2016 *Science* Breakthrough of the Year Runner Up



Science
AAAS

Pocket-Size DNA Sequencer

Document 22

The Scientist's Top Ten Innovations 2016

3 **Pacific Biosciences >>**
The Sequel System

5 **Thermo Fisher Scientific >>**
LentiArray CRISPR Libraries

10 **Thermo Fisher Scientific >>**
GeneArt Platinum Cas9 Nuclease

Document 23

Genomes In The News…

Document 24

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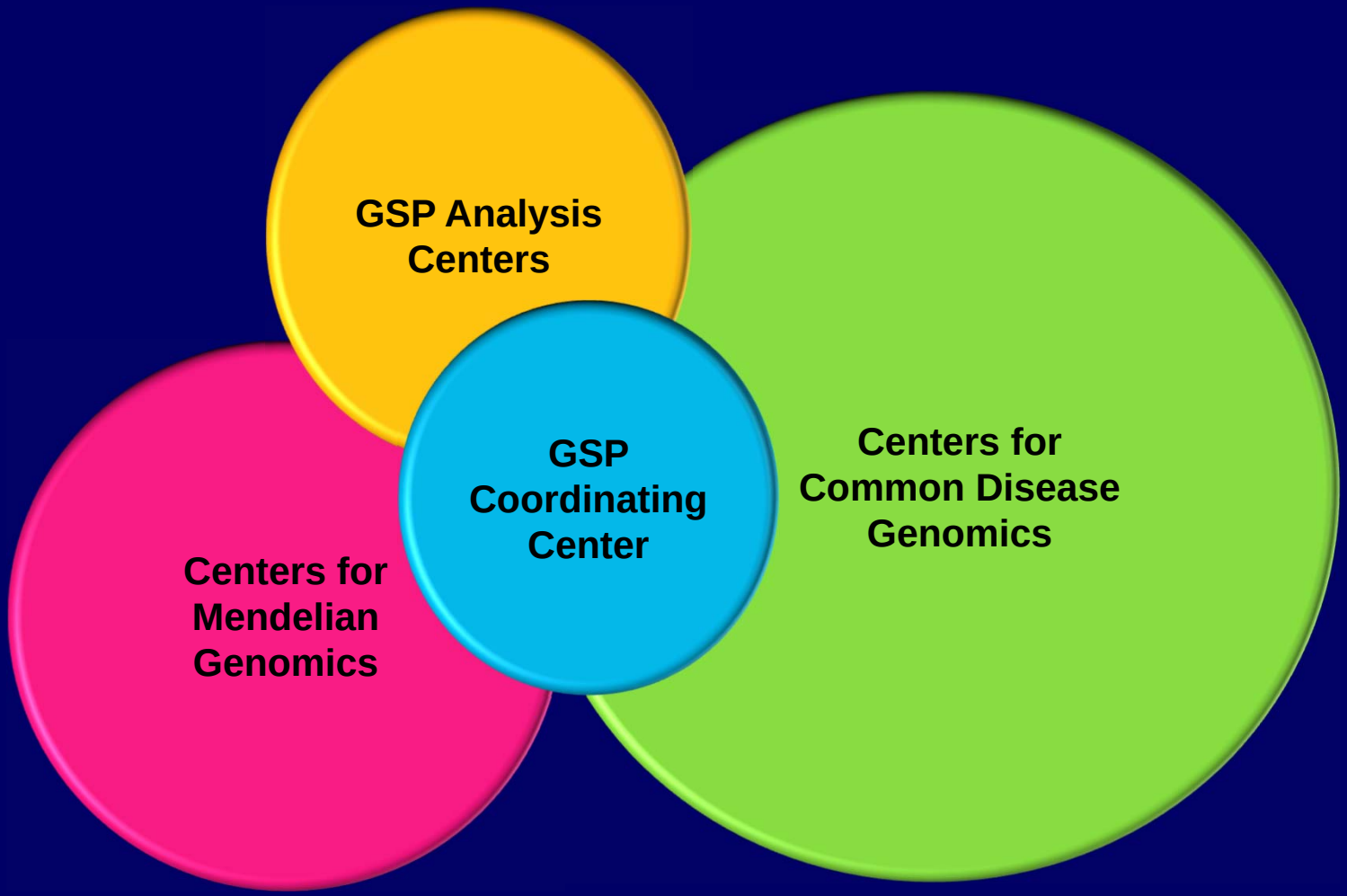
Genome Sequencing Program



Document 25

Genome Sequencing Program

- **Centers for Common Disease Genomics (CCDGs)**
  - Cardiovascular Diseases
  - Neuropsychiatric Diseases
  - Autoimmune/Inflammatory Diseases
  - ~ 18,000 whole genomes sequenced
  - ~ 19,000 whole exomes sequenced
- **Centers for Mendelian Genomics (CMGs)**
  - ~ 200 articles published
  - ~ 1,000 genes discovered
  - ~ 19,000 whole exomes sequenced

Nature 2017; 541(7636):169-175. doi: 10.1038/nature20805. Epub 2017 Jan 4.

Nature 2017; doi: 10.1038/nature21386. Epub ahead of print

MC3 *synapse.org/MC3*

Search | Register | Sign in | Help

Synapse ID: syn7214402 DOI: doi:10.7303/syn7214402 **Storage Location:** Synapse Storage

Annotations

Wiki | Files | Tables | Discussion | Docker beta

MC3

- Sample Selection
- Data Processing
- Annotation
- Filters
- Caveats
- Additional Links
- Acknowledgements

<<

TCGA Unified Ensemble "MC3" Call Set

This wiki page provides documentation for the pancan.merged.v0.2.6.PUBLIC.maf dataset. This is the public, open-access, dataset of somatic mutation calls (SNVs and indels) produced as part of the capstone project based on the full complement of cases in The Cancer Genome Atlas (TCGA).. The file was produced using six different algorithms from four centers on over 10,000 tumor/normal pairs in TCGA. This effort is referred to within the TCGA Network as MC3 ("Multi-Center Mutation Calling in Multiple Cancers")

Members of the TCGA PanCanAtlas project should go syn5917256 for the working files (both open-access and controlled-access) for the PanCanAtlas project.

Acknowledgement:

In addition to citing the dataset, people who use the MC3 file should include the following in their acknowledgements: "The results <published or shown> here are in whole or part based upon data generated by the TCGA Research Network: http://cancergenome.nih.gov/ as outlined in the TCGA publications guidelines http://cancergenome.nih.gov/publications/publicationguidelines

Questions or concerns should be directed to Discussion Board

Document 26

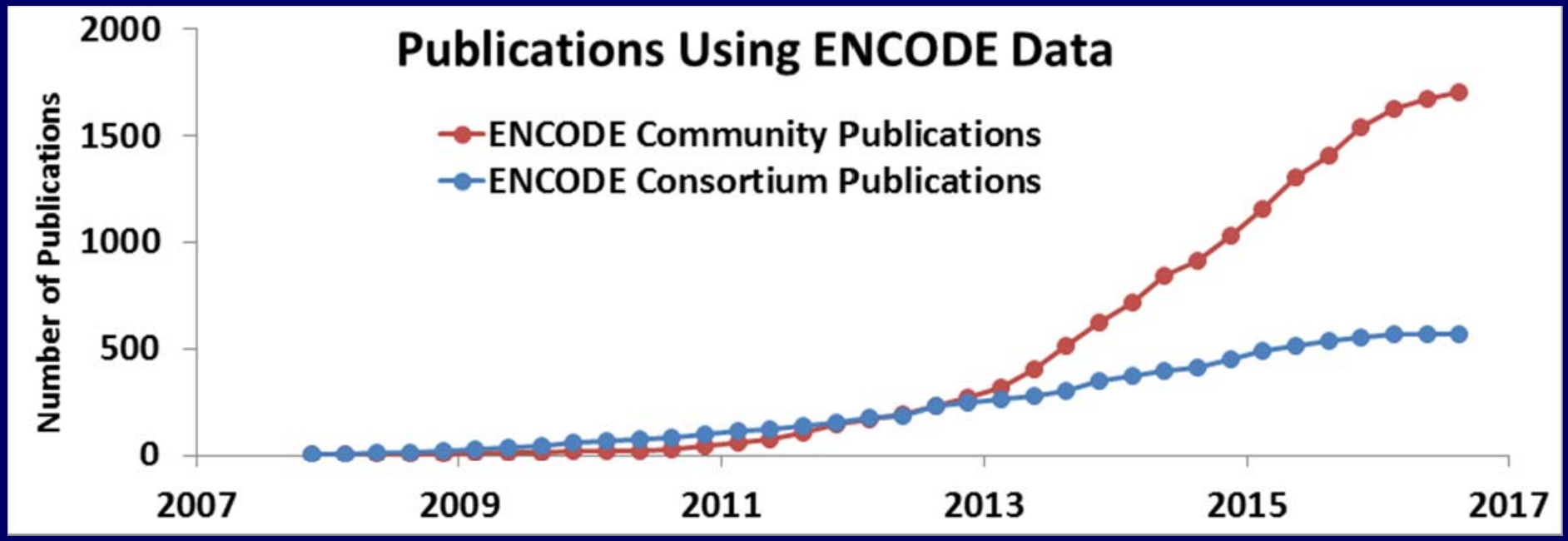
Technology Development Program

- **Novel Nucleic Acid Sequencing Technology Development**
  - **RFA-HG-15-031 (to 33; R01, R21, and R43/44)**
  - **Upcoming due date: June 15, 2017**
- **Novel Genomic Technology Development**
  - **PAR-16-14 (to 17; R01, R21, R43/44, and R44)**
  - **Upcoming due date: October 31, 2017**

Encyclopedia of DNA Elements (ENCODE)

- **ENCODE Outreach and Collaboration**

  ENCODE-DREAM In Vivo Transcription Factor-Binding Site Prediction Challenge



Encyclopedia of DNA Elements (ENCODE)

- 4th phase of ENCODE grants
- Expand the catalog
- NEW Functional Characterization Centers

Funded Initiative	# of Awards
Mapping Centers	8
Functional Characterization Centers	5
Computational Centers	6
Data Analysis Center (DAC)	1
Data Coordinating Center (DCC)	1

Document 28

Centers of Excellence in Genomic Science (CEGS) Program

Two new CEGS awards:

- **Broad Institute**
  Center for Cell Circuits
- **University of Chicago**
  Center for Dynamic RNA Epitranscriptomes

GWAS Catalog

The NHGRI-EBI Catalog of published genome-wide association studies

Examples: breast cancer, rs7329174, Yang, 2q37.1, HBS1L

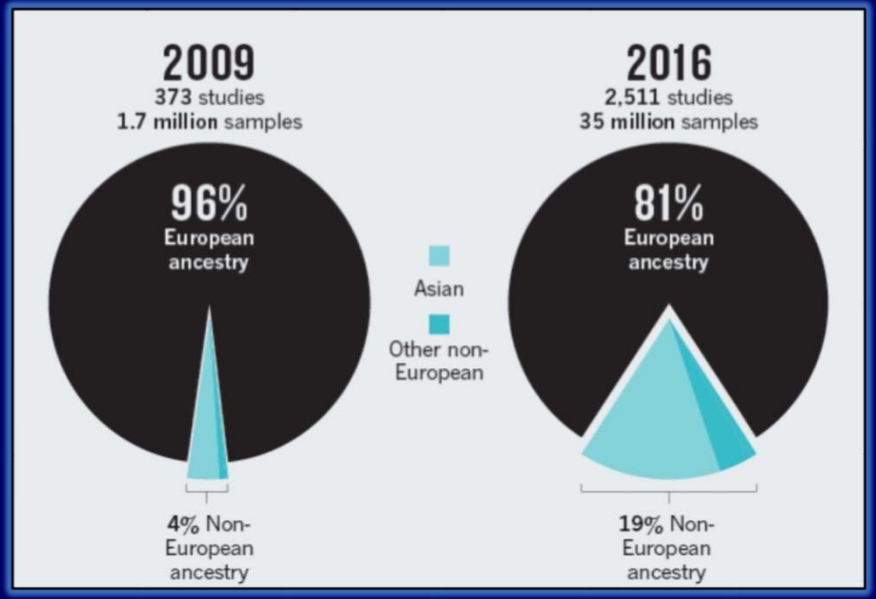
Certain drugs may be less effective, or even unsafe, in some populations because of genetic differences.

Genomics is failing on diversity

An analysis by **Alice B. Popejoy** and **Stephanie M. Fullerton** indicates that some populations are still being left behind on the road to precision medicine.

Nature. 2016;538(7624):161-164. doi: 10.1038/538161a.

Ancestry Distribution of GWAS Participants



- ***Nature* commentary highlights GWAS Catalog data**
- **Updated, comprehensive analysis underway**

Document 30

PhenX Toolkit

90 new and updated measures added

PhenX Toolkit

Integration by larger research programs

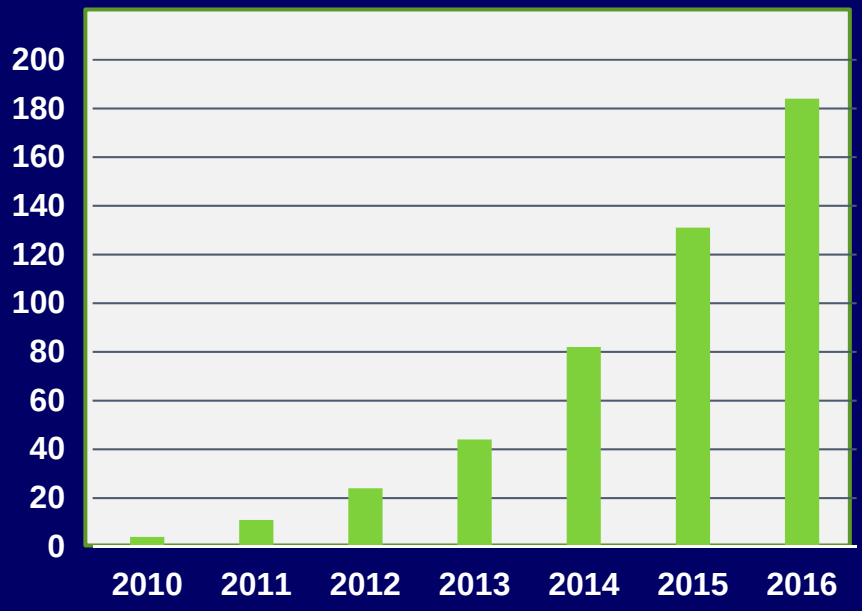
ECHO
Environmental Influences on Child Health Outcomes

Adolescent Brain Cognitive Development
Teen Brains. Today's Science. Brighter Future.

All of Us
THE FUTURE OF HEALTH BEGINS WITH YOU
The Precision Medicine Initiative

PATH
Population Assessment of Tobacco and Health
A collaboration between the NIH and FDA

FOAs citing PhenX (cumulative)



dbGaP mapping

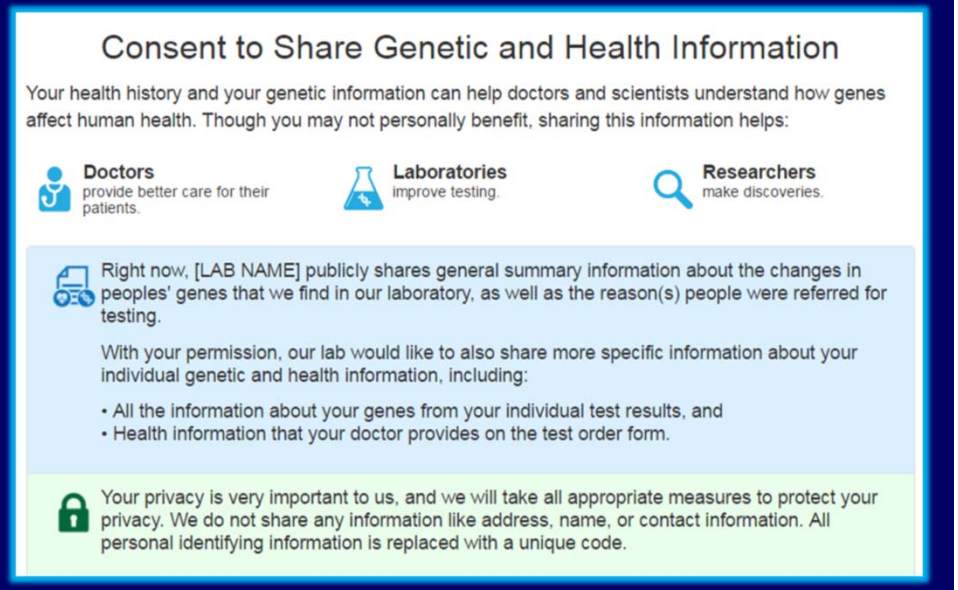
dbGaP Study containing PhenX "Alcohol 30 Day Freq" measure
Candidate Gene Association Resource (CARe)
NEIGHBOR Consortium Glaucoma GWAS
Genetic Multiple Sclerosis Association (GeneMSA)
The Vaginal Microbiome: Disease, Genetics, and the Environment
GenADA/LONG/Imaging (Genetic Alzheimer's Disease Associations)

Document 31

ClinGen: Sharing Data. Building Knowledge. Improving Care.

RFA-HD-17-001

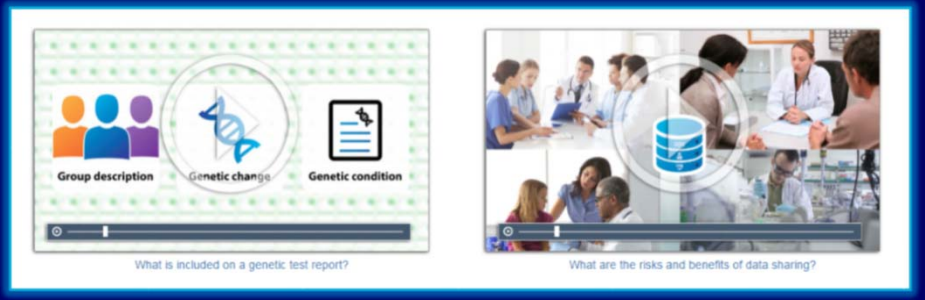
NICHD Genomic Clinical Variant Expert Curation Panels



Gene Curation

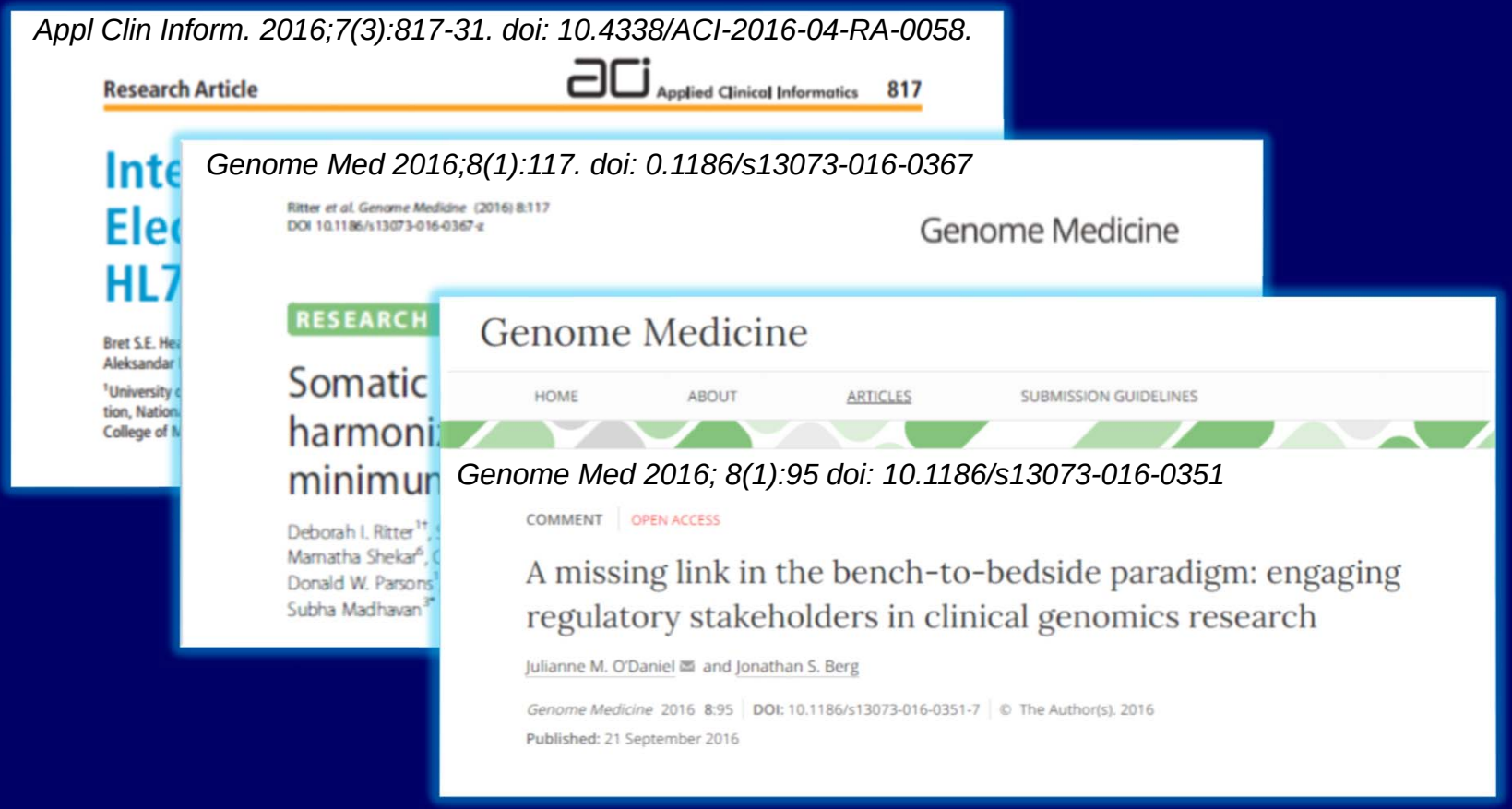
Variant Curation

Actionability Curation



Document 32

ClinGen: Sharing Data. Building Knowledge. Improving Care.



Document 32

Clinical Sequencing Exploratory Research Program

- Enrolled 5,135 adults and 1,320 children
- 288 publications, 18 working group publications

Clinical Sequencing Exploratory Research Program

Genet Med 2016; doi: 10.1038/gim.2016.152

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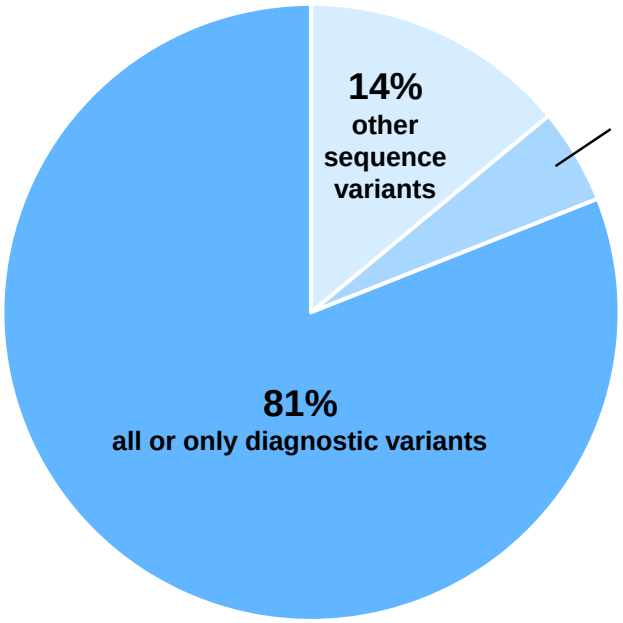
ORIGINAL RESEARCH ARTICLE | Genetics inMedicine

A survey of current practices for genomic sequencing test interpretation and re

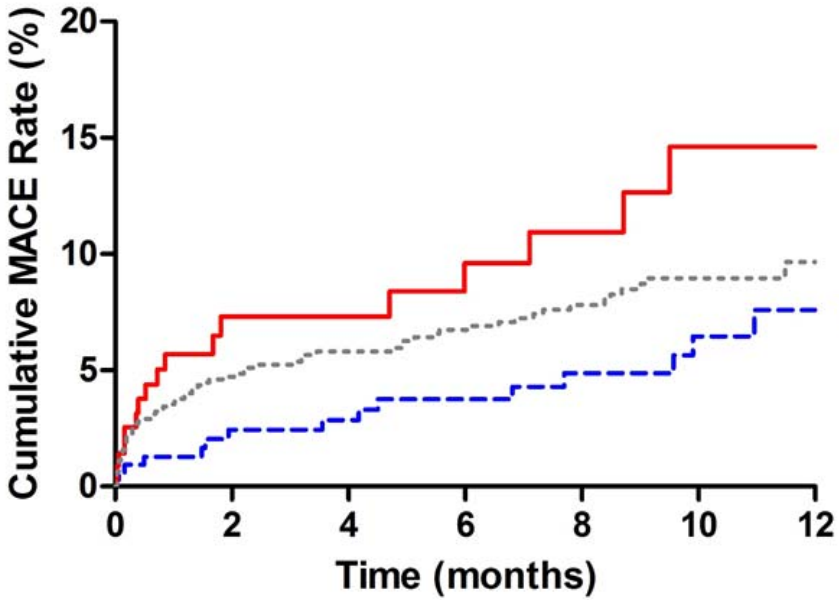
Julianne M. O'Daniel, MS[1], H
Sherri J. Bale, PhD[4], Jonathan S.
Elizabeth C. Chao, MD[7,8], Wendy K. C
Soma Das, PhD[12], Joshua L. Deignan
Arezou A. Ghazani, PhD[15]
Kelly D. Farwell Hagman,
Lucia A. Hindorff, PhD, MPH[29]
Amy Knight Johnson, MS[12], Lindsey Mig
Sumit Punj, PhD[22], C. Sue Richa
Nancy B. Spinner, PhD[11], Sha
Yaping Ya



Orthogonal confirmation practices among labs (n = 21)

Implementing Genomics In Practice (IGNITE) Network

MACE Risk Halved through PGx Prescribing



LOF_CLOP
NON-LOF
LOF_ALT

Log-rank p=0.02
Log-rank p=0.2

Adjusted Hazard Ratio
LOF-CLOP vs LOF Alt.: 2.21
LOF-Alt. vs non-LOF: 0.81

Kaplan-Meier Survival Curve

LOF = Loss of function

Newborn Sequencing In Genomic medicine and public HealTh (NSIGHT)

PEDIATRICS

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Newborn Sequencing in Genomic Medicine and Public Health

Jonathan S. Berg, MD, PhD,[a] Pankaj B. Agrawal, MD, MMSc,[b,c] Donald B. Bailey Jr., PhD,[d] Alan H. Beggs, PhD,[c] Steven E. Brenner, PhD,[e] Amy M. Brower, PhD,[f] Julie A. Cakici, BA, BSN,[g] Ozge Ceyhan-Birsoy, PhD,[h] Kee Chan, PhD,[i] Flavia Chen, MPH,[j] Robert J. Currier, PhD,[k] Dmitry Dukhovny, MD, MPH,[l] Robert C. Green, MD, MPH,[m] Julie Harris-Wai, MPH, PhD,[j,n] Ingrid A. Holm, MD, MPH,[c] Brenda Iglesias,[o] Galen Joseph, PhD,[p] Stephen F. Kingsmore, MD, DSc,[g] Barbara A. Koenig, PhD,[n] Pui-Yan Kwok, MD, PhD,[j,q] John Lantos, MD,[r] Steven J. Leeder, PharmD, PhD,[r] Megan A. Lewis, PhD,[d] Amy L. McGuire, JD, PhD,[s] Laura V. Milko, PhD,[a] Sean D. Mooney, PhD,[t] Richard B. Parad, MD, MPH,[u] Stacey Pereira, PhD,[s] Joshua Petrikin, MD,[r] Bradford C. Powell, MD, PhD,[a] Cynthia M. Powell, MD,[v] Jennifer M. Puck, MD,[w] Heidi L. Rehm, PhD,[h] Neil Risch, PhD,[j] Myra Roche, MS,[v] Joseph T. Shieh, MD, PhD,[j,x] Narayanan Veeraraghavan, PhD,[g] Michael S. Watson, MS, PhD,[f] Laurel Willig, MD, MS,[r] Timothy W. Yu, MD, PhD,[c] Tiina Urv, PhD,[y] Anastasia L. Wise, PhD[o]

Document 35

4th ELSI Congress

Expanding the ELSI Universe #ELSICon

- Co-sponsored by NHGRI, the Jackson Laboratory, Columbia University Medical Center, and UCONN Health
- Keynote Speakers:
  - Eric Dishman
  - Alondra Nelson
  - Wylie Burke
  - James Evans
  - Pearl O'Rourke
- Topics:
  - Precision medicine
  - Genome sequencing enters the clinic
  - Genes, ancestry, and identity

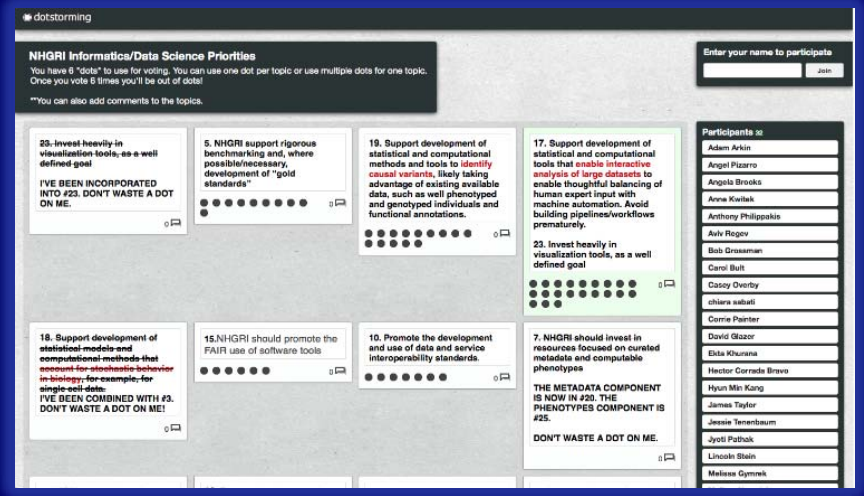
Document 36

Computational Genomics and Data Science Program

- **Workshop in Bethesda September 2016**

  Co-chairs: Mike Boehnke, Carol Bult, Trey Ideker, Aviv Regev, and Lincoln Stein

- **Goal: Elicit discussion about NHGRI's future extramural computational genomics and data science portfolio**



- **Final report will be presented at May Council meeting**

Document 37

Small Business Grants

Small Business	Phase I Proof of Principle	Phase II Pre-Commercialization
Innovation Research (SBIR)	18	13
Technology Transfer (STTR)	6	1
Total	24	14

Document 38

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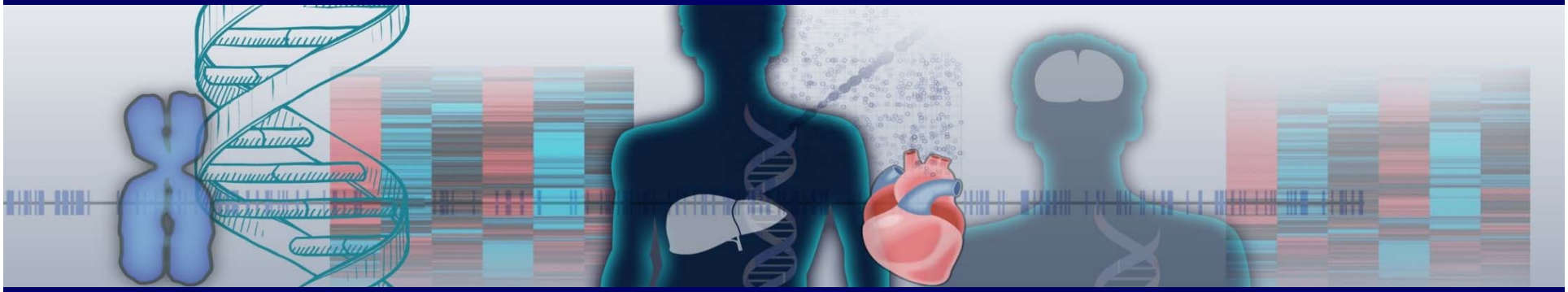
Genotype-Tissue Expression (GTEx)



- Enrollment complete (965 donors)
- Version 7 data release in summer 2017

  >600 whole-genome sequences

  RNA-Seq data on >12,000 samples

dbGaP GENOTYPES and PHENOTYPES

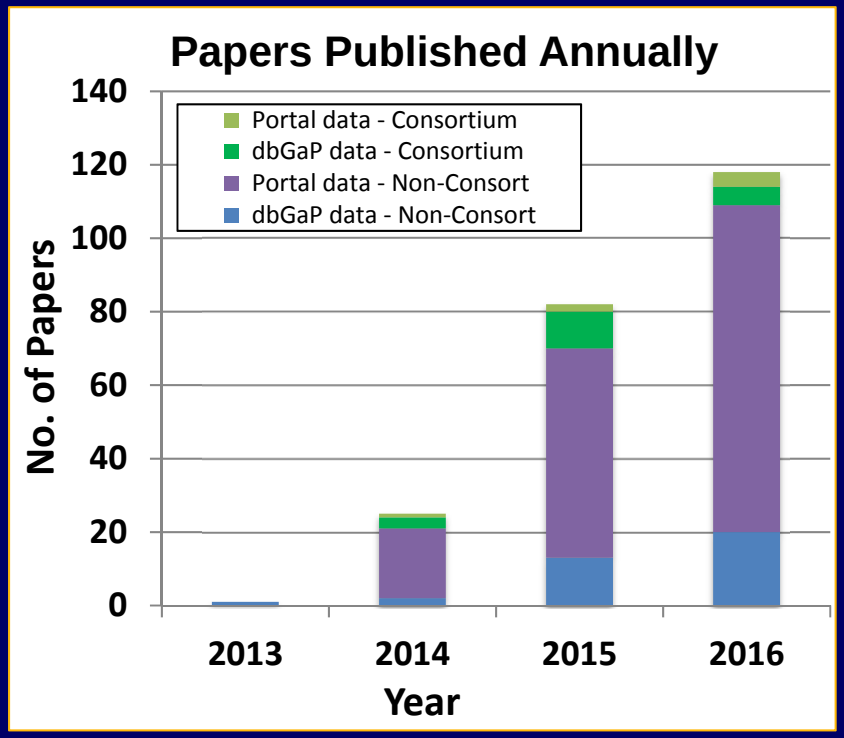
Second most downloaded data set after TCGA in FY16 (531 requests vs 1478)

Common Fund (CF) Genotype-Tissue Expression Project (GTEx)

Barcelona, Spain in April 2017

GTEx Portal

- >9,000 registered users from >90 countries
- 48,826 gene-expression profiles downloaded
- >220 papers using GTEx data, mostly from non-consortium members



UCSC

Ensembl

GeneCards HUMAN GENE DATABASE

THE HUMAN PROTEIN ATLAS

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Human Heredity and Health in Africa (H3Africa)

- 9th Consortium Meeting in October 2016

  Opening by Dr. Ameenah Gurib-Fakim, President of Mauritius

- Last Consortium meeting of Phase 1: May 2017
- Review of Phase 2 applications: March 2017

Document 40

Undiagnosed Diseases Network (UDN)

Undiagnosed Diseases Network | UDN Site Locations

Highlights

Undiagnosed Diseases Network sticks around

The Undiagnosed Diseases Network, an NIH Common Fund program aimed at solving challenging medical mysteries, isn't going anywhere anytime soon. The program has just approved funding through 2022. With this investment, the UDN will continue to accept participants with undiagnosed conditions and hopes to better understand how to become self-sustaining in the future. Funding announcements are planned for Summer 2017, pending available funds.

1062 Applications
414 Acceptances

APPLY

Document 41

Precision Medicine Initiative

The Precision Medicine Initiative® (PMI) Cohort Program

All of Us℠ | The Precision Medicine Initiative®

THE FUTURE OF HEALTH BEGINS WITH YOU

"These survey results suggest that people from all walks of life will be interested in the cohort program."

—Dave Kaufman, Ph.D., Program Director, National Human Genome Research Institute

PLOS ONE

RESEARCH ARTICLE

A Survey of U.S Adults' Opinions about Conduct of a Nationwide Precision Medicine Initiative® Cohort Study of Genes and Environment

David J. Kaufman[1]*, Rebecca Baker[2], Lauren C. Milner[2], Stephanie Devaney[2], Kathy L. Hudson[2]

1 National Human Genome Research Institute, Division of Genomics and Society, National Institutes of Health, Rockville, MD, United States of America, **2** National Institutes of Health, Office of the Director, Bethesda, MD, United States of America

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All of Us℠
THE FUTURE OF HEALTH BEGINS WITH YOU
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New England Precision Medicine Consortium
Boston, MA
Hudson River Health Care
Peekskill, NY
Community Health Center, Inc.
Middletown, CT
Illinois Precision Medicine Consortium
Chicago, IL
Columbia/Cornell/Harlem Hospital HPO
New York, NY
California Precision Medicine Consortium
San Diego, CA
Precision Approach to healthCARE Enrollment Site
Pittsbugh, PA
Scripps and Vibrent Participant Technologies/ Direct Volunteer Opps
La Jolla, CA
Geisinger Health System
Danville, PA
Cherokee Health Systems
Knoxville, TN
San Ysidro Health Center
San Ysidro, CA
Eau Claire Cooperative Health Center
Columbia, SC
University of Arizona - Banner Health Enrollment Center
Tucson, AZ
Jackson-Hinds Comprehensive Health Center
Jackson, MS
Vanderbilt/Broad/Verily Data and Research Support Core
Nashville, TN
Federally Qualified Health Centers
Regional Medical Centers
Biobank
Data and Research Support Core
Participant Technology Center
Recruitment at VA Hospitals
Direct volunteer recruitment nationwide
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Director's Report Outline

I. General NHGRI Updates

II. General NIH Updates

III. General Genomics Updates

IV. NHGRI Extramural Research Program

V. NIH Common Fund/Trans-NIH

VI. NHGRI Division of Policy, Communications, and Education

VII. NHGRI Intramural Research Program

ASHG-NHGRI Fellowships

2017-2018 Application Process Open

- Genetics and Public Policy Fellowship
- Genetics and Education Fellowship
- Application deadline: April 24, 2017

Document 43

Genome: Unlocking Life's Code Exhibition

Travel Schedule

2017

April 1-May 29
Peoria Riverfront Museum
Peoria, IL

June 12-September 11
Health Museum
Houston, TX

September 30-January 1
Science North
Sudbury, Ontario, Canada

Document 44

Genome: Unlocking Life's Code Exhibition

Website Award

Document 44

Genomic Literacy, Education, and Engagement (GLEE) Initiative

- Possible launching of a national campaign to enhance genomic literacy
- Proposed target audiences: K-16, public, and healthcare professionals
- Strategic Visioning Meeting: March 2017

2017 NHGRI Short Course in Genomics

K-12, Community College, and Tribal College Faculty

National Human Genome Research Institute
Short Course in Genomics

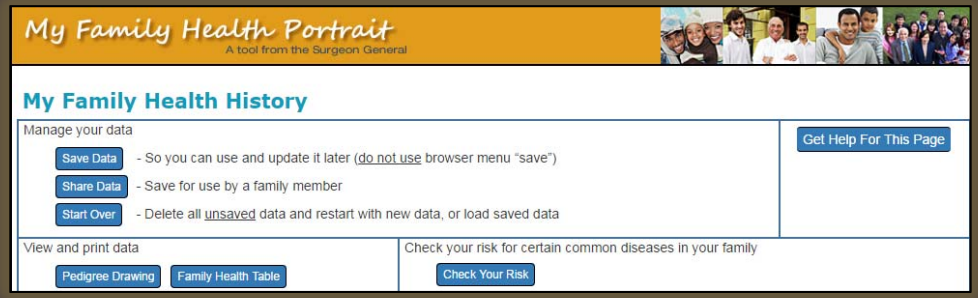
Applications Open: Feb. 2017

Nurses, Physician Assistants, and Educators

National Human Genome Research Institute
Short Course in Genomics
Nurse, Physician Assistant and Faculty Track

Applications Open: March 2017

My Family Health Portrait



- Family history tool website revised to improve the user experience
- 'NLM Hackathon' to extend interoperability and expose programmers to family history and relevant resources

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International Summit in Human Genetics and Genomics

- Five-year initiative (2016-2020)
- Help developing nations build expertise in genetics and genomics
- September 2016: 19 participants from 13 countries across the globe

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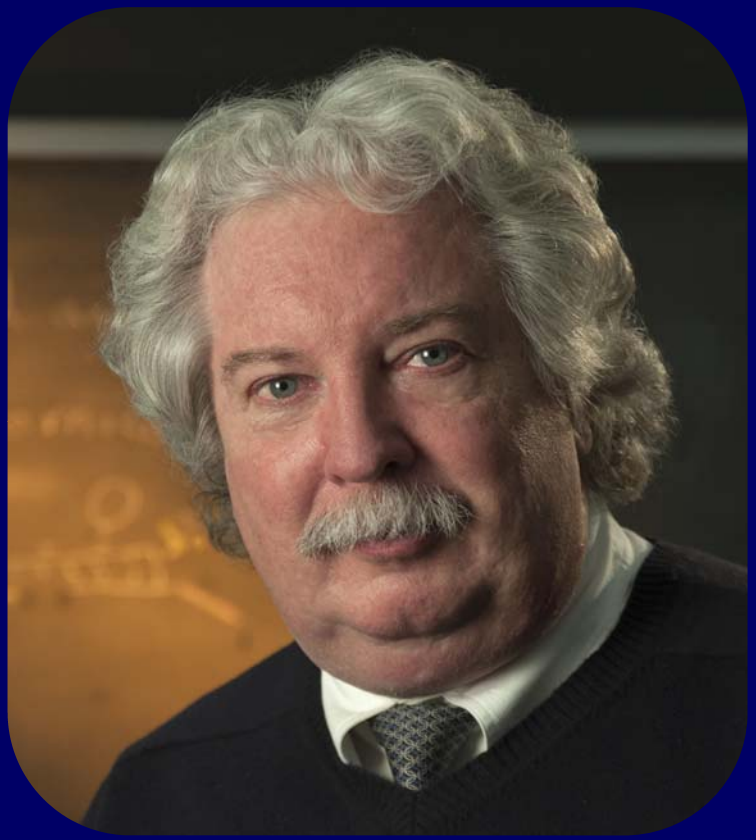
Master, American College of Rheumatology

AMERICAN COLLEGE OF RHEUMATOLOGY
EDUCATION • TREATMENT • RESEARCH

Dan Kastner, M.D., Ph.D.

Document 48

International Genetic Epidemiology Society Leadership Award



INTERNATIONAL GENETIC EPIDEMIOLOGY SOCIETY

Alec Wilson, Ph.D.

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NHGRI Intramural Research Highlights

PNAS

Proceedings of the National Academy of Sciences of the United States of America

Biallelic hypomorphic mutations in a linear deubiquitinase define otulipenia, an early-onset autoinflammatory disease

Human Molecular Genetics

Systemic AAV9 gene therapy improves the lifespan of mice with Niemann-Pick disease, type C1

npj | Regenerative Medicine

Extracellular Hsp60 triggers tissue regeneration and wound healing by regulating inflammation and cell proliferation

To receive *The Genomics Landscape*, go to list.nih.gov

Search for NHGRILANDSCAPE

Past issues can be accessed at: genome.gov/27527308

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Thanks!

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