Million Veteran Program

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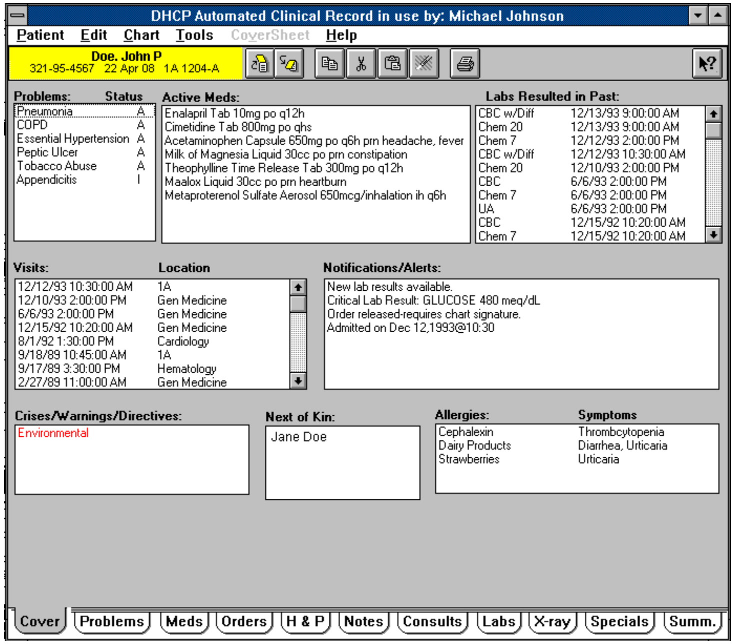
Population Research in the VA Healthcare System

- VA ideal setting for nested large-scale population research
  - Stable and altruistic Veteran population of 8 million using the system each year
  - Outstanding electronic medical record; fully integrated; data reaching back as far as 20 years; access to CMS and NDI data
  - Intramural research program with diverse clinician and doctoral expertise
  - >70% of investigators are clinicians linking research with Veterans' needs
  - An example of team science and big data within VA infrastructure, involving administrative, technical, ethical and scientific challenges.



Doe. John P
321-95-4567 22 Apr 08 1A 1204-A

Problems:	Status
Pneumonia	A
COPD	A
Essential Hypertension	A
Peptic Ulcer	A
Tobacco Abuse	A
Appendicitis	I

Active Meds:
Enalapril Tab 10mg po q12h
Cimetidine Tab 800mg po qhs
Acetaminophen Capsule 650mg po q6h prn headache, fever
Milk of Magnesia Liquid 30cc po prn constipation
Theophylline Time Release Tab 300mg po q12h
Maalox Liquid 30cc po prn heartburn
Metaproterenol Sulfate Aerosol 650mcg/inhalation ih q6h

Labs Resulted in Past:	
CBC w/Diff	12/13/93 9:00:00 AM
Chem 20	12/13/93 9:00:00 AM
Chem 7	12/12/93 2:00:00 PM
CBC w/Diff	12/12/93 10:30:00 AM
Chem 20	12/10/93 2:00:00 PM
CBC	6/6/93 2:00:00 PM
Chem 7	6/6/93 2:00:00 PM
UA	6/6/93 2:00:00 PM
CBC	12/15/92 10:20:00 AM
Chem 7	12/15/92 10:20:00 AM

Visits:	Location
12/12/93 10:30:00 AM	1A
12/10/93 2:00:00 PM	Gen Medicine
6/6/93 2:00:00 PM	Gen Medicine
12/15/92 10:20:00 AM	Gen Medicine
8/1/92 1:30:00 PM	Cardiology
9/18/89 10:45:00 AM	1A
9/17/89 3:30:00 PM	Hematology
2/27/89 11:00:00 AM	Gen Medicine

Notifications/Alerts:
New lab results available.
Critical Lab Result: GLUCOSE 480 meq/dL
Order released-requires chart signature.
Admitted on Dec 12,1993@10:30

Crises/Warnings/Directives:
Environmental

Next of Kin:
Jane Doe

Allergies:	Symptoms
Cephalexin	Thrombcytopenia
Dairy Products	Diarrhea, Urticaria
Strawberries	Urticaria

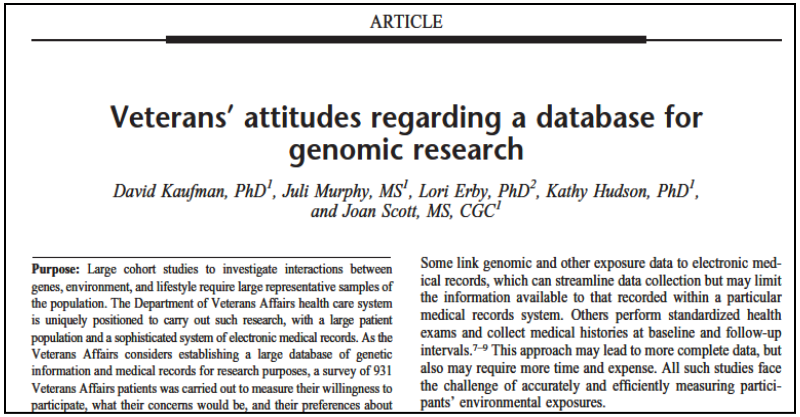
Million Veteran Program (MVP)

- Enroll up to one million users of the VHA into an observational mega-cohort
  - Blood collection for storage in biorepository for future research
  - Collect self-reported health and lifestyle information
  - Access to electronic medical record
  - Ability to recontact participants

Million Veteran Program

Veteran Consultation Projects – Genomic Medicine Research

- 83% said program should be done
- 71% said they would participate
- 61% also said they would:
  - Allow medical records from non-VA health care to be added to the database
  - Have follow up exams over time
- Most respondents were willing to participate under both opt-in (80%) and opt-out (69%) models
- Stronger preferences for the opt-in approach were expressed among younger Veterans and Hispanic Veterans



ARTICLE

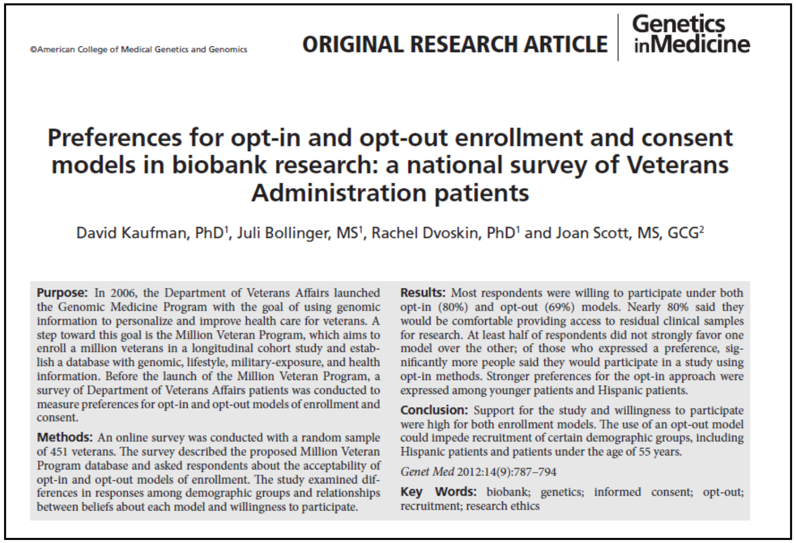
Veterans' attitudes regarding a database for genomic research

David Kaufman, PhD[1], Juli Murphy, MS[1], Lori Erby, PhD[2], Kathy Hudson, PhD[1], and Joan Scott, MS, CGC[1]

Purpose: Large cohort studies to investigate interactions between genes, environment, and lifestyle require large representative samples of the population. The Department of Veterans Affairs health care system is uniquely positioned to carry out such research, with a large patient population and a sophisticated system of electronic medical records. As the Veterans Affairs considers establishing a large database of genetic information and medical records for research purposes, a survey of 931 Veterans Affairs patients was carried out to measure their willingness to participate, what their concerns would be, and their preferences about

Some link genomic and other exposure data to electronic medical records, which can streamline data collection but may limit the information available to that recorded within a particular medical records system. Others perform standardized health exams and collect medical histories at baseline and follow-up intervals.[7–9] This approach may lead to more complete data, but also may require more time and expense. All such studies face the challenge of accurately and efficiently measuring participants' environmental exposures.

Genetics in Medicine, Vol 11:329-337, May 2009



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ORIGINAL RESEARCH ARTICLE

Genetics inMedicine

Preferences for opt-in and opt-out enrollment and consent models in biobank research: a national survey of Veterans Administration patients

David Kaufman, PhD[1], Juli Bollinger, MS[1], Rachel Dvoskin, PhD[1] and Joan Scott, MS, GCG[2]

Purpose: In 2006, the Department of Veterans Affairs launched the Genomic Medicine Program with the goal of using genomic information to personalize and improve health care for veterans. A step toward this goal is the Million Veteran Program, which aims to enroll a million veterans in a longitudinal cohort study and establish a database with genomic, lifestyle, military-exposure, and health information. Before the launch of the Million Veteran Program, a survey of Department of Veterans Affairs patients was conducted to measure preferences for opt-in and opt-out models of enrollment and consent.

Methods: An online survey was conducted with a random sample of 451 veterans. The survey described the proposed Million Veteran Program database and asked respondents about the acceptability of opt-in and opt-out models of enrollment. The study examined differences in responses among demographic groups and relationships between beliefs about each model and willingness to participate.

Results: Most respondents were willing to participate under both opt-in (80%) and opt-out (69%) models. Nearly 80% said they would be comfortable providing access to residual clinical samples for research. At least half of respondents did not strongly favor one model over the other; of those who expressed a preference, significantly more people said they would participate in a study using opt-in methods. Stronger preferences for the opt-in approach were expressed among younger patients and Hispanic patients.

Conclusion: Support for the study and willingness to participate were high for both enrollment models. The use of an opt-out model could impede recruitment of certain demographic groups, including Hispanic patients and patients under the age of 55 years.

Genet Med 2012:14(9):787–794

Key Words: biobank; genetics; informed consent; opt-out; recruitment; research ethics

Genetics in Medicine, Vol 14: 787-794, September 2012

Research Challenges –
Standardization and Uniformity of Processes

- Recruitment
- Consent & HIPAA
- Self reported data collections
- Sample collections
- Analytics
- Access
- Data sharing and repurposing

- *A partnership with Veterans*

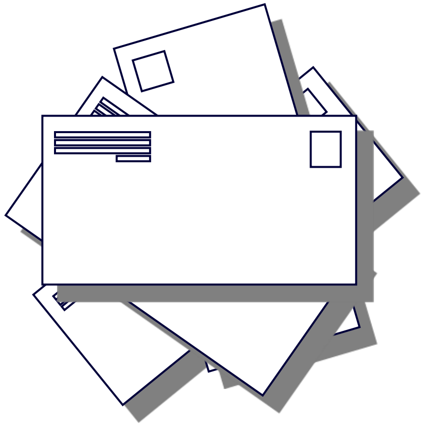
Distribution of MVP Sites

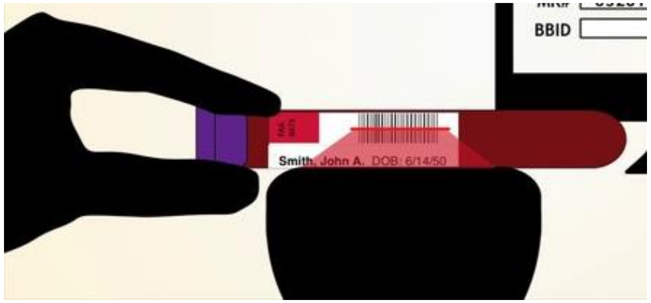
★ = Actively Recruiting

● = Closed to Recruitment

MVP Recruitment and Enrollment

- Invitational Mailing/Appointment Mailing
  - Invitation letter, Baseline Survey, MVP Brochure
  - Appointment letter, Informed consent language
- Walk-in recruitment
- Study visit
  - Informed consent/HIPAA
  - Blood collection
- Thank You Mailing
  - Thank you letter, Lifestyle Survey
- Specimens sent daily
  - Receive & process 400-600/d
  - Stretch 1000/d





VA Central Biorepository

MVP Governance Structure

- VA Central Office Operations (GMP/CSP)
  - Oversees day-to-day operations at CSP coordinating centers (e.g., funding/resources, policy guidance, decision making)
  - VA Central IRB (internal)
    - VA Office of Research Oversight (external)
  - Provides coordination and facilitates communication among different groups
- MVP Steering Committee
  - *Mission:* In balance with Central Office (Operations), provides additional guidance and ideas to expand the Million Veteran Program. In coordination with the MVP Subcommittees, oversees organizational activities and makes recommendations to guide the Million Veteran Program
- MVP Subcommittees (dedicated to specific areas)
- Genomic Medicine Program Advisory Committee

MVP Recruitment to Date

Invitation mailings sent	2.78 Million
Expressed interest by mail	13.9%
Optout	13.5%
Completed Baseline Surveys	461,709
Consented Veterans	362,662
Specimens in Lab	360,200
Unscheduled (proportion)	48.3%
Upcoming appointments	5,400
Call volume	Over 120,000 inbound

As of March 30, 2015

Characteristics of MVP Enrollees

Age:	<50 yrs	13.8%
	50-69 yrs	58.7%
	≥70 yrs	27.5%
Sex:	Male	91.9%
	Female	8.1%
Race:	White	77.5%
	African-Amer	18.5%
	[other]	3.3%
	[Native]	0.7%
Ethnicity:	Hispanic	5.4%

Branch:	Army	50.6%
	Navy	21.2%
	Air Force	16.7%
	Marines	10.1%
	Nat'l Guard	0.5%
	Coast Guard	0.8%
	[other]	0.1%
Era:	thru 6/1950	5.3%
	7/50-1/55	5.0%
	2/55-7/64	7.1%
	8/64-4/75	41.0%
	5/75-7/90	11.8%
	8/90-current	10.0%
	[multiple]	19.8%

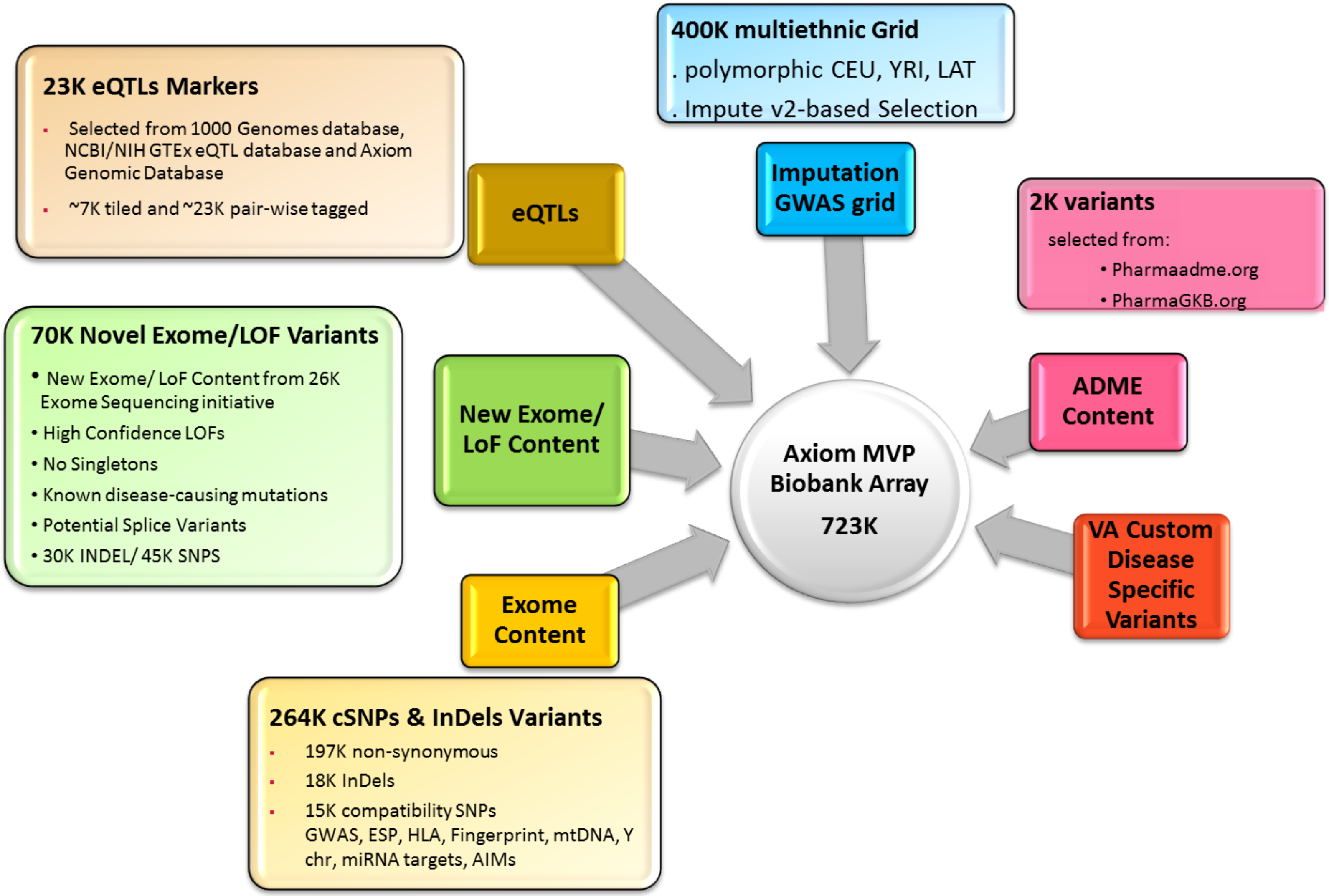
Note: based on N≤275,806 enrollees

Sample Breakout by Analysis Type (FY12-14)

	SNP Genotype	**Exome**	**Genome**
MVP	408,113	18,611	612
CSP 572 (functional disability of SZ and BPI) cases	9,356	9,356	285
CSP 575* (PTSD)	*52,238*	*2,366*	N/A
ALS			999

*estimated number of PTSD cases from MVP cohort, based on self-reported survey data

Axiom MVP Biobank Array



23K eQTLs Markers

- Selected from 1000 Genomes database, NCBI/NIH GTEx eQTL database and Axiom Genomic Database
- ~7K tiled and ~23K pair-wise tagged

400K multiethnic Grid

. polymorphic CEU, YRI, LAT

. Impute v2-based Selection

2K variants

selected from:

- Pharmaadme.org
- PharmaGKB.org

70K Novel Exome/LOF Variants

- New Exome/ LoF Content from 26K Exome Sequencing initiative
- High Confidence LOFs
- No Singletons
- Known disease-causing mutations
- Potential Splice Variants
- 30K INDEL/ 45K SNPS

264K cSNPs & InDels Variants

- 197K non-synonymous
- 18K InDels
- 15K compatibility SNPs
GWAS, ESP, HLA, Fingerprint, mtDNA, Y chr, miRNA targets, AIMs

MVP Genomic Analyses: Whole Exome Sequencing

- Contracts started 2013

- 50x depth coverage across 95% exome regions (~5-15 GB data/sample)
  - Personalis—Illumina
  - Claritas Genomics—Ion Torrent platform
- Data sent back to VA= raw data and annotated (fastq, BAM files, .vcf, quality scores and other metadata)
- Schizophrenia, Bipolar disorder, oversampled (>50%) for MVP African Americans

CLARITAS GENOMICS

Personalis

MVP Genomic Analyses: Whole Genome Sequencing

- Contracts started 2012
- 30x depth coverage over 90% genome (~300GB data/sample)
  - Personalis—Illumina platform
  - Claritas Genomics—Ion Torrent platform
- Data sent back to VA as raw data and annotated (fastq, BAM files, .vcf, quality scores, some additional metadata)
- Samples = ALS, Schizophrenia, Bipolar disorder, and Exceptionally aged MVPers (95+)

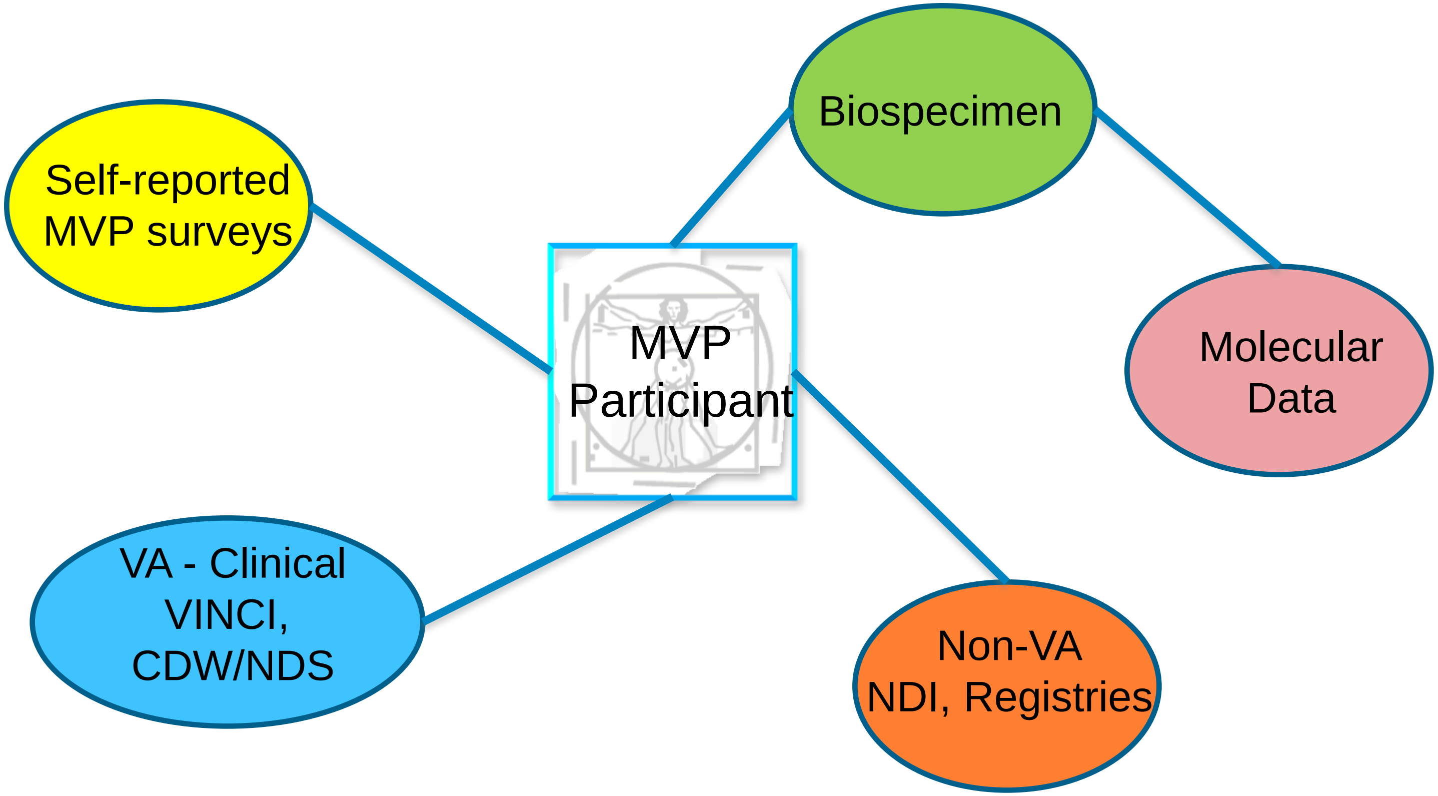
CLARITAS GENOMICS

Personalis

Ongoing and Upcoming Sequence Data Analysis

- Whole Genome and Exome Sequence Data
  - Boston VA and Palo Alto VA
  - Perform quality check on variant data
  - Concordance with SNP arrays
    - ti/tv, het/hom, private variants, novel variants, missingness rates, gender, ethnicity
    - % un/mapped reads; coverage
    - % of exonic, intronic, intergenic variants
  - Aid in analysis of case/control studies
    - ALS; Schizophrenia/Bipolar; Exceptionally Aged MVPers (95+)
  - Development and testing of Analysis Pipeline VAPAHCS/Stanford
  - Cross-comparison of data derived from the Illumina and Ion Torrent platforms

MVP Data Universe



Self-reported MVP surveys

Biospecimen

MVP Participant

Molecular Data

VA - Clinical VINCI, CDW/NDS

Non-VA NDI, Registries

Other Data Sources

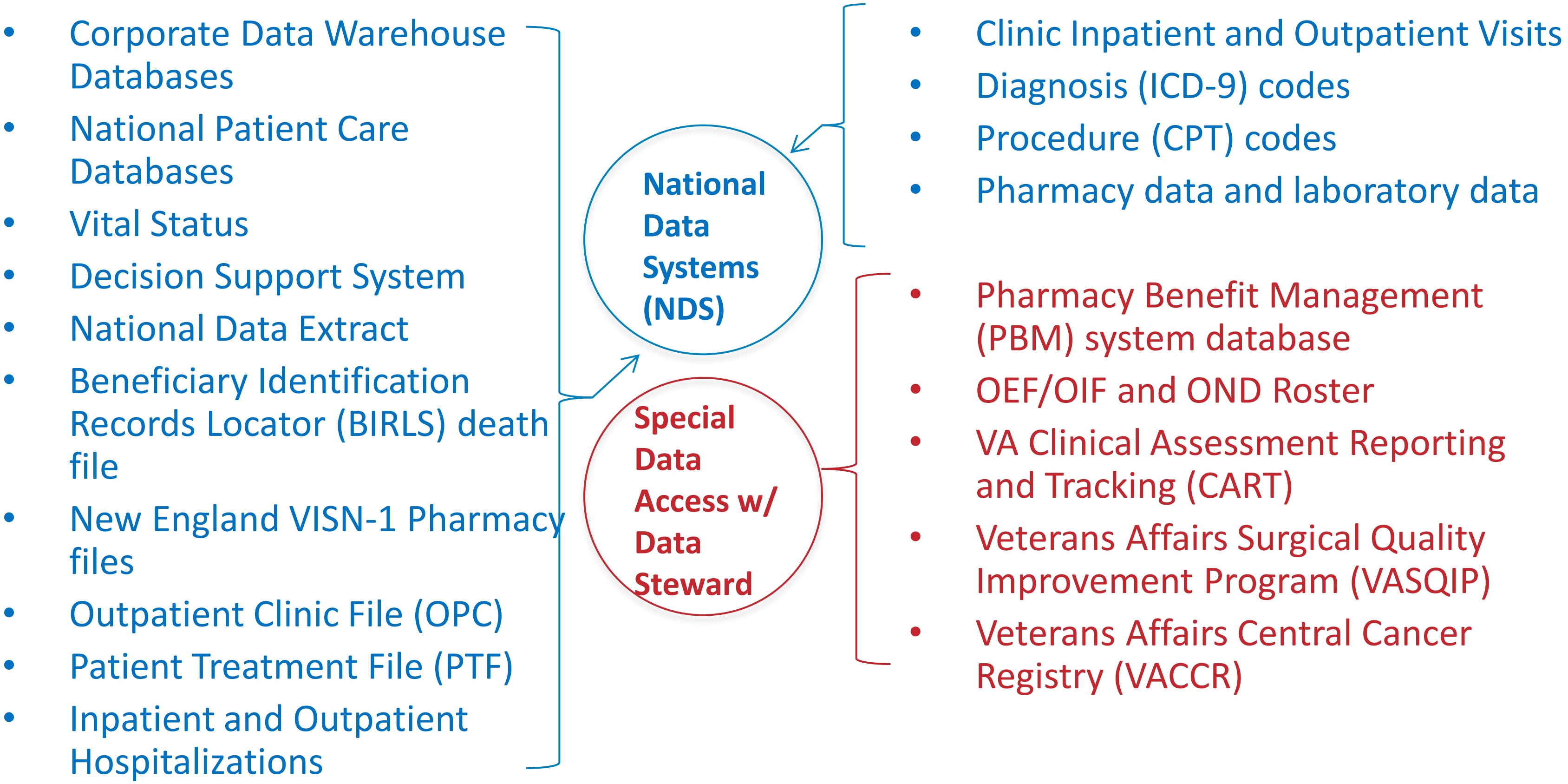
MVP Data

- Self-Reported Survey Data:
  - Lifestyle Survey Data (Personal Information, Well-Being, Activity, Health, Military Experience, Dietary Intake, Medication, Habits)
  - Baseline Survey (Health, Military Experiences, family medical history)
- Genetic Data
  - Genotype data
  - Sequence data

Other Data

- VA Healthcare System Data
- Other Data
  - National Death Index (NDI)
  - Centers for Medicare and Medicaid Services (CMS)
  - State Mortality Data

VA Data Sources



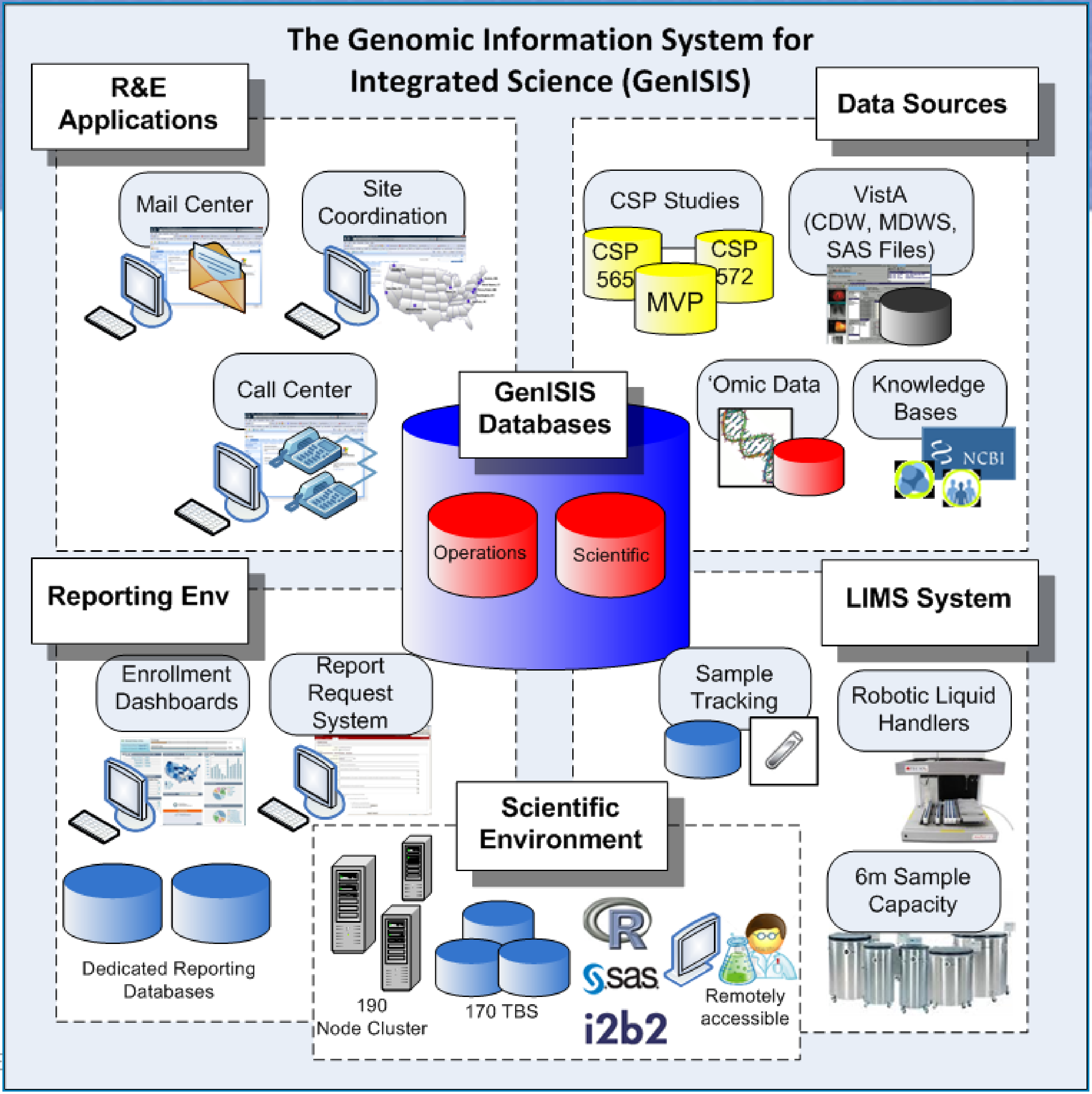
- Corporate Data Warehouse Databases
- National Patient Care Databases
- Vital Status
- Decision Support System
- National Data Extract
- Beneficiary Identification Records Locator (BIRLS) death file
- New England VISN-1 Pharmacy files
- Outpatient Clinic File (OPC)
- Patient Treatment File (PTF)
- Inpatient and Outpatient Hospitalizations

National Data Systems (NDS)

Special Data Access w/ Data Steward

- Clinic Inpatient and Outpatient Visits
- Diagnosis (ICD-9) codes
- Procedure (CPT) codes
- Pharmacy data and laboratory data

- Pharmacy Benefit Management (PBM) system database
- OEF/OIF and OND Roster
- VA Clinical Assessment Reporting and Tracking (CART)
- Veterans Affairs Surgical Quality Improvement Program (VASQIP)
- Veterans Affairs Central Cancer Registry (VACCR)



The Genomic Information System for Integrated Science (GenISIS)

R&E Applications
- Mail Center
- Site Coordination
- Call Center

Data Sources
- CSP Studies
  - CSP 565
  - CSP 572
  - MVP
- VistA (CDW, MDWS, SAS Files)
- 'Omic Data
- Knowledge Bases

GenISIS Databases
- Operations
- Scientific

Reporting Env
- Enrollment Dashboards
- Report Request System
- Dedicated Reporting Databases

LIMS System
- Sample Tracking
- Robotic Liquid Handlers
- 6m Sample Capacity

Scientific Environment
- 190 Node Cluster
- 170 TBS
- R
- sas
- i2b2
- Remotely accessible

GenISIS Secure Computing Environment

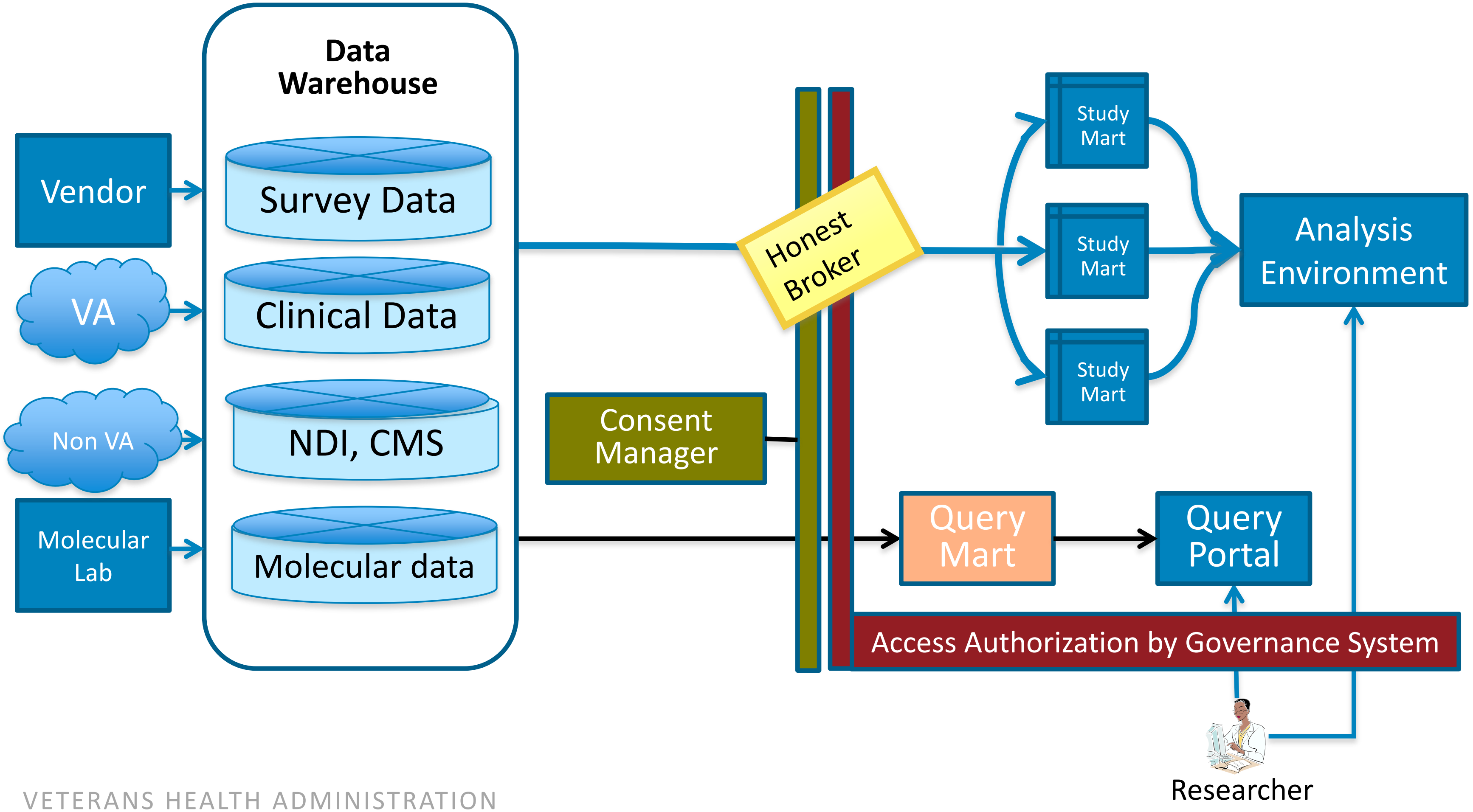
- Provides a secure computing environment with analytical tools
- Allows users to submit and manage their HPC jobs from a web dashboard
- Users authenticated by their VA network accounts
- Default 5 TB space allocated to each project, plus additional scratch space
- Analytic software available (PLINK, R/Bioconductor, SAS, Matlab, Perl/Bioperl, JMP Genomics and others) and will be updated based on user needs

VINCI: Resource for Clinical Data

- Veterans Informatics and Computing Infrastructure (VINCI) securely hosts select data from national VA databases
- Provides data to credentialed VA investigators with appropriate approvals
- Data updated nightly for many clinical domains
- Provides services and tools for data provisioning, curating, NLP, analytics and data services, annotation and chart review, feasibility determination, and application development
  - Established an enclave with the MVP crosswalk within VINCI

VINCI
VA
Informatics and
Computing
Infrastructure

System Architecture



MVP Phenotyping Activities

Complex Phenotypes

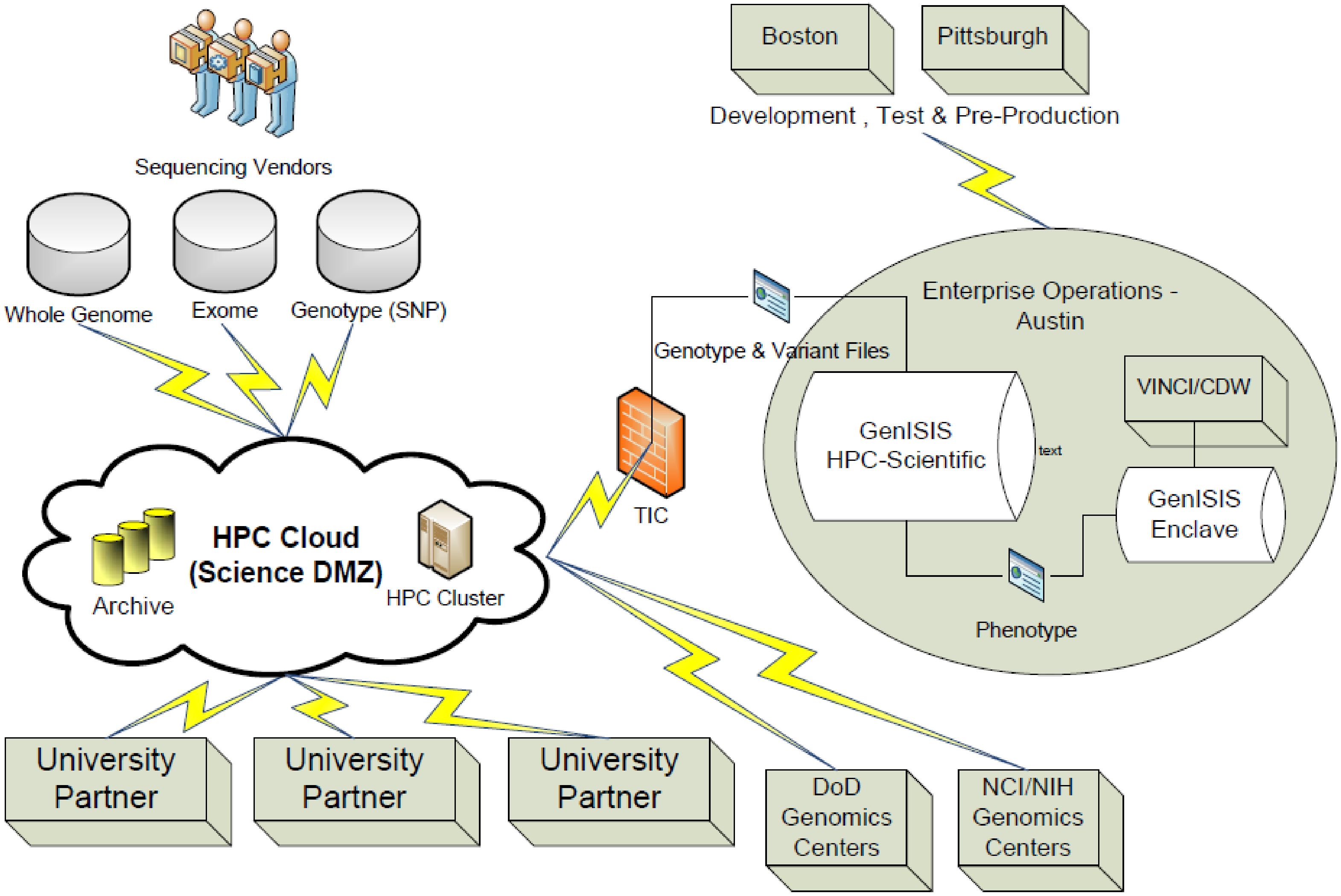
- Disease
  - Myocardial infarction (MI)
  - Stroke
  - Unstable angina with revascularization
  - Acute congestive heart failure
  - Death from cardiovascular disease
  - Vascular procedure
  - Posttraumatic stress disorder (PTSD)
  - Schizophrenia
  - Bipolar disorder
  - Traumatic brain injury
  - Depression
  - Vascular dementia
  - Cognitive impairment
  - Type 2 diabetes mellitus
- Other
  - Creatinine trajectory
  - Glucose trajectory

Core Variables

- Demographics
  - Age
  - Sex
  - Race
- Laboratory values
  - Total cholesterol
  - HDL, LDL
  - Albumin
  - Serum creatinine
  - Triglycerides
- Medications
- Other characteristics
  - Blood pressure
  - Height/weight/BMI
  - Smoking
  - Alcohol consumption
  - Combat exposure

Algorithm Development Validation Methods

MVP "To-Be" Architecture



MVP Data Access Roll-Out

- Alpha Test Projects (Ongoing)
  - CSP572 (Genetics of functional disability in Schizophrenia and Bipolar Disorder); ~9500 cases deeply phenotyped; enrollment completed; Controls from MVP
    - genotyping and exome sequencing to be completed in FY15; data analysis in FY16
  - CSP575B (Genetics of PTSD in Veterans; Cases and Controls with self-reported combat exposure from MVP; ~10,000 cases
    - deep phenotyping ongoing; QC of genotype data ongoing; data analysis in FY 16
- Beta Test Projects
  - RFA for analysis of 200K genotyped dataset

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VA Central Office

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MVP Steering Committee and Subcommittees

Steering Committee: John Concato, M.D., M.S., M.P.H., Co-Chair; J. Michael Gaziano, M.D., M.P.H., Co-Chair; Rayan Al Jurdi, M.D.; James L. Breeling, M.D.; Louis Fiore, M.D., M.P.H., ex-officio; John B. Harley, M.D., Ph.D.; Elizabeth Hauser, Ph.D.; Grant Huang, M.P.H., Ph.D. Ex-Officio; Phil Tsao, Ph.D.; Janet D. Crow, ORD Liaison; Philip D. Harvey, Ph.D.; Timothy J. O'Leary, M.D., Ph.D., Ex-Officio; Stephen G. Waxman, M.D., Ph.D.; Peter W. F. Wilson, M.D.

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Thank you!