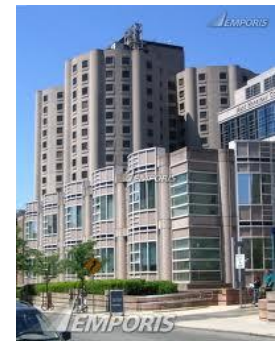


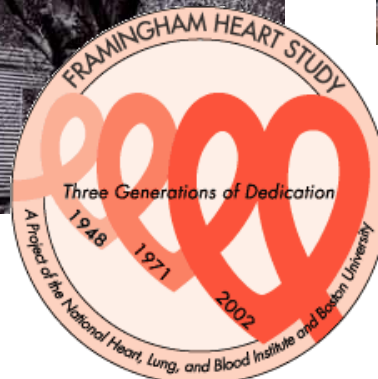
Million Veteran Program (MVP): A Mega-Cohort within a Healthcare System

J. Michael Gaziano, MD, MPH

**Scientific Director, MAVERIC and PI, MVP, VA Boston Healthcare System
Chief, Division of Aging, Brigham and Women's Hospital
Professor of Medicine, Harvard Medical School**



Transformative “Big Data” Problems



Evolution of Epidemiology

- Descriptive phase

The Black Death



Bruegel's
Triumph of Death
c. 1556

Evolution of Epidemiology

- Descriptive phase



The Black Death



Bruegel's
Triumph of Death
c. 1556

Evolution of Epidemiology

- Descriptive phase

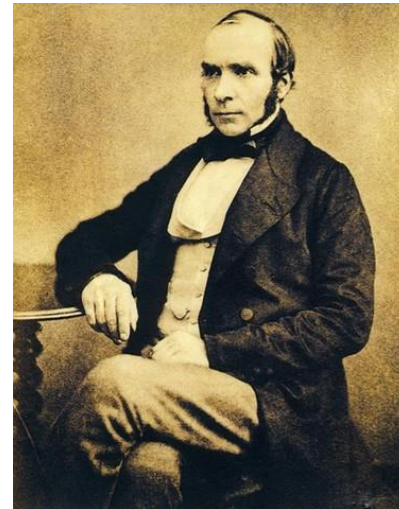
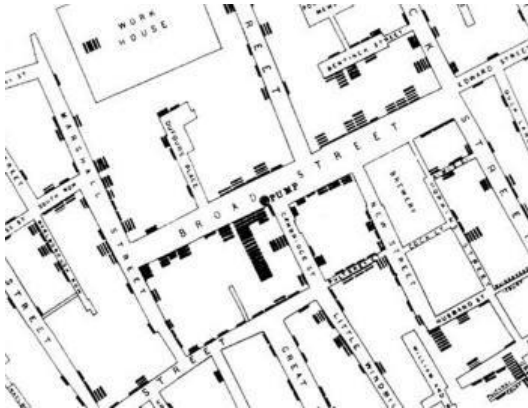
The Black Death



Bruegel's
Triumph of Death
c. 1556

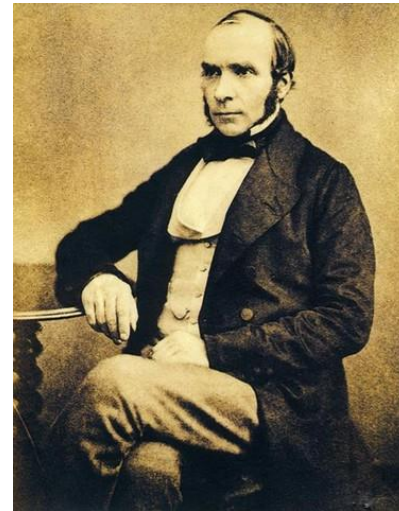
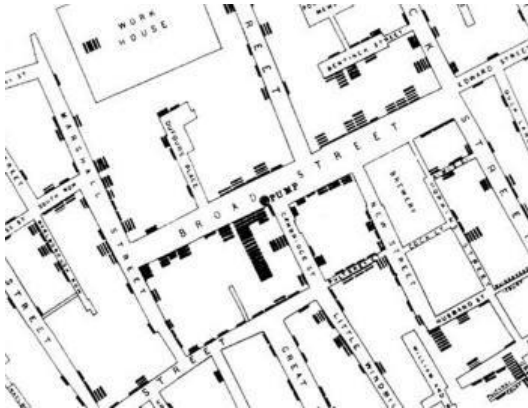
Evolution of Epidemiology

- Descriptive phase
- Pre-analytic phase



Evolution of Epidemiology

- Descriptive phase
- Pre-analytic phase
- Analytic phase



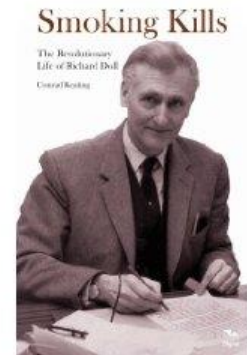
Evolution of Epidemiology

- **Descriptive phase**
- **Pre-analytic phase**
- **Analytic phase**
 - Case-control, Cohort studies, RCTs

Evolution of Epidemiology

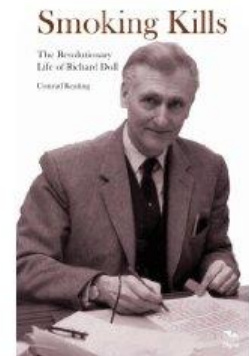
- Descriptive phase
- Pre-analytic phase
- Analytic phase
 - Case-control, Cohort studies, RCTs

	Disease	No Disease
Smoking	8	2
No Smoking	2	8



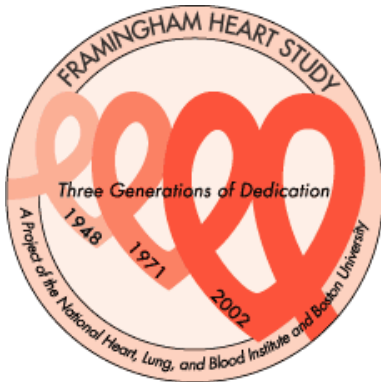
Evolution of Epidemiology

- Descriptive phase
- Pre-analytic phase
- Analytic phase
 - Case-control, Cohort studies, RCTs



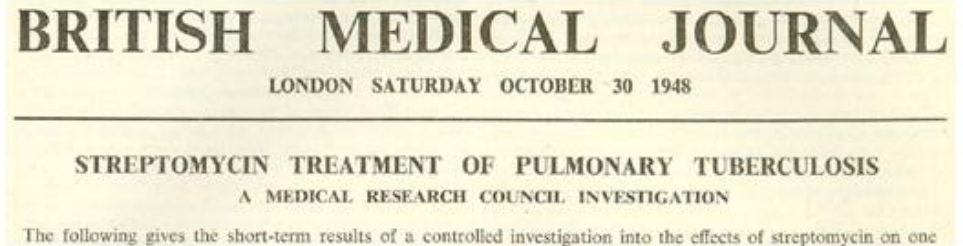
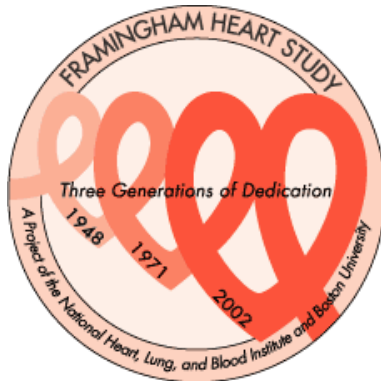
Evolution of Epidemiology

- Descriptive phase
- Pre-analytic phase
- Analytic phase
 - Case-control, Cohort studies, RCTs



Evolution of Epidemiology

- Descriptive phase
- Pre-analytic phase
- Analytic phase
 - Case-control, Cohort studies, RCTs

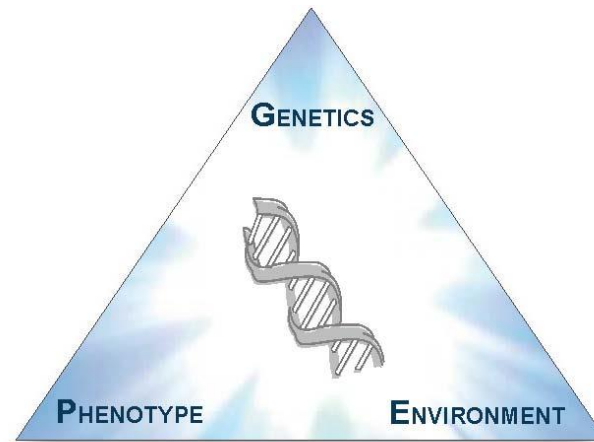


Evolution of Epidemiology

- **Descriptive phase**
- **Pre-analytic phase**
- **Analytic phase**
 - Case-control, Cohort studies, RCTs

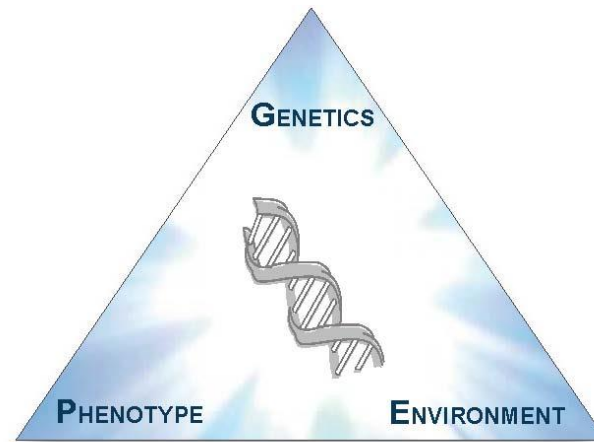
Evolution of Epidemiology

- Descriptive phase
- Pre-analytic phase
- Analytic phase
 - Case-control, Cohort studies, RCTs



Evolution of Epidemiology

- Descriptive phase
- Pre-analytic phase
- Analytic phase
 - Case-control, Cohort studies, RCTs
- Super Analytic Phase: Mega-Biobanks



Nesting Population Research in the VA Healthcare System

VA ideal setting for nested large-scale population research

- Stable and willing 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
- Research infrastructure with diverse expertise
- Prototypes for health system based research:
 - **Million Veteran Program**
 - **Pragmatic trial of HCTZ vs Chlorthalidone**

The screenshot displays the DHCP Automated Clinical Record interface for patient Doe, John P. (321-95-4567, 22 Apr 08, 1A 1204-A). The interface is organized into several sections:

- Problems:** A list of medical conditions with status indicators (A for Active, I for Inactive).

Problems	Status
Pneumonia	A
COPD	A
Essential Hypertension	A
Peptic Ulcer	A
Tobacco Abuse	A
Appendicitis	I
- Active Meds:** A list of current medications and their dosages.

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:** A list of recent laboratory tests and their results.

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:** A list of patient visits with dates and times.

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:** A section for alerts and notifications.

New lab results available.
Critical Lab Result: GLUCOSE 480 mg/dL.
Order released-requires chart signature.
Admitted on Dec 12, 1993@10:30
- Crises/Warnings/Directives:** A section for crises, warnings, and directives.

Environmental
- Next of Kin:** A section for next of kin information.

Jane Doe
- Allergies:** A list of patient allergies.

Allergies
Cephalexin
Dairy Products
Strawberries
- Symptoms:** A list of patient symptoms.

Symptoms
Thrombocytopenia
Diarrhea, Urticaria
Urticaria

The interface includes a menu bar at the top with options: Patient, Edit, Chart, Tools, CoverSheet, and Help. At the bottom, there is a tabbed navigation bar with options: Cover, Problems, Meds, Orders, H & P, Notes, Consults, Labs, X-ray, Specials, and Summ.

Million Veteran Program (MVP)

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

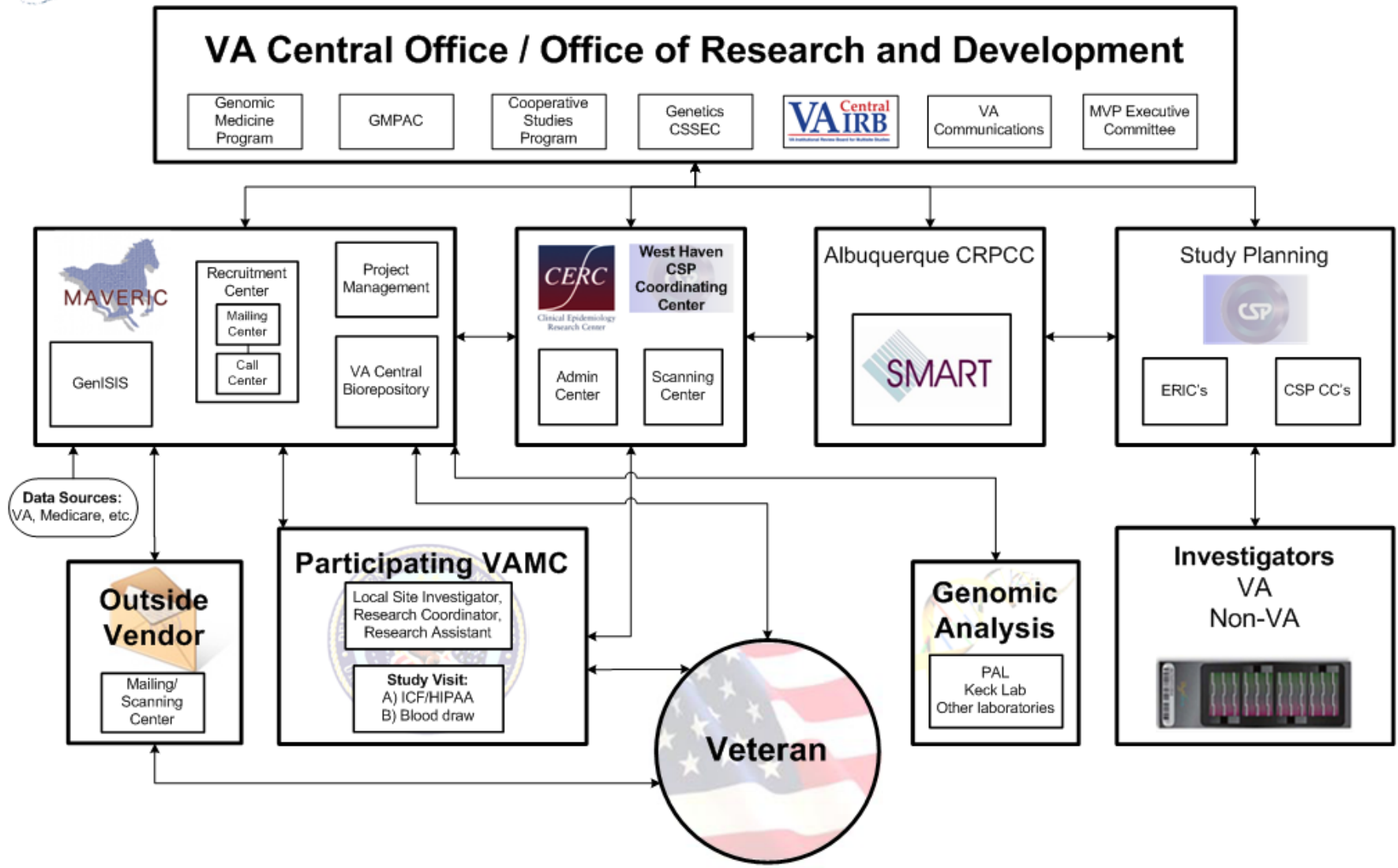


MVP Organizational Structure



Million Veteran Program (MVP): A Partnership with Veterans

02/07/2011

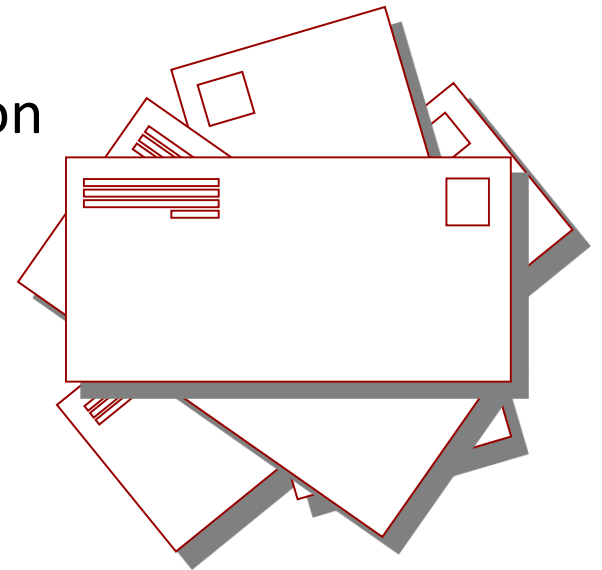


MVP Design and Implementation

- Recruitment and Enrollment
- Biorepository
- Biochemical Analysis
- IT/Informatics
- Epidemiology and Phenotyping
- Current Projects

MVP Recruitment and Enrollment

- Invitational Mailing
 - Invitation letter, Baseline Survey, MVP Brochure
- Appointment Mailing
 - Appointment letter, Informed consent language
- Study visit procedures
 - Informed consent/HIPAA, Blood collection
- Thank you Mailing
 - Thank you letter, Lifestyle Survey



Baseline Survey

Collects basic demographic, health, and lifestyle information including:

- Health status
- Military experience
- Medical history
- Healthcare utilization
- Family pedigree
- Family history of disease

1992421457

Section A: Personal Information

1. What is today's date?

		/			/				
mm			dd			yyyy			

2. What is your date of birth?

		/			/				
mm			dd			yyyy			

3. What is your gender?

☐ Male
☐ Female

4. Are you Spanish, Hispanic, or Latino?

☐ No, not Spanish, Hispanic, Latino
☐ Yes, Mexican, Mexican American, Chicano
☐ Yes, Puerto Rican
☐ Yes, Cuban
☐ Yes, other Spanish, Hispanic, Latino

5. What is your race? (Mark all that apply)

☐ White
☐ Black/African-American
☐ American Indian/Alaska Native
☐ Chinese
☐ Japanese
☐ Asian Indian
☐ Other Asian
☐ Filipino
☐ Pacific Islander
☐ Other

6. Where are your ancestors originally from?

(Mark all that apply)

☐ Africa
☐ East Asia/Pacific Ocean region
☐ Middle East
☐ North America
☐ Northern Europe
☐ Southern Europe
☐ South America
☐ Southwest Asia

7. What is the highest degree or level of school you have completed?

☐ Less than high school
☐ High school diploma / GED
☐ Some college credit, but no degree
☐ Associate's degree (e.g., AA, AS)
☐ Bachelor's degree (e.g., BA, BS)
☐ Master's degree (e.g., MA, MS, MBA)
☐ Professional or Doctorate degree

8. What is your current marital status?

☐ Married
☐ Civil commitment
☐ Cohabitating
☐ Separated
☐ Divorced
☐ Widowed
☐ Never married

9. Including yourself, how many people currently live in your household?

1	2	3	4	5	6	7	8	9 +
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. Which income category represents the total income of your household from all sources (before taxes and deductions) during the last 12 months?

☐ Less than \$10,000
☐ \$10,000 - \$19,999
☐ \$20,000 - \$29,999
☐ \$30,000 - \$39,999
☐ \$40,000 - \$49,999
☐ \$50,000 - \$59,999
☐ \$60,000 - \$74,999
☐ \$75,000 - \$99,999
☐ \$100,000 - \$149,999
☐ \$150,000 or more
☐ Prefer not to answer

GMP SF V1 09/14/2010

Page 1 of 10

MVP Study Visit

- Study visit procedures
 - Obtain consent/HIPAA
 - Collect blood specimen
 - Walk-ins given printed baseline form
 - Given MVP pin
- All aspects are automated using SharePoint and GenISIS.



Thank You / Lifestyle Survey

- Thank you letter
- Lifestyle Survey
 - Occupational history
 - Combat history
 - Exercise habits
 - Mental health
 - Environmental exposures
 - Dietary habits

5800572636

Personal Information

1. What is today's date?

mm / dd / yyyy

2. What is your date of birth?

mm / dd / yyyy

3. What is your current body weight?

pounds

4. Compared to one year ago, has your weight changed?

☐ Yes, lost weight
☐ Yes, gained weight
☐ No, weigh about the same

5. When you gain weight, where on your body do you mostly add the weight?

☐ Waist and/or upper body
☐ Hips, bottom, and/or upper thighs
☐ Evenly over your body
☐ Don't gain weight

6. In your opinion, are you:

☐ Underweight
☐ Normal weight
☐ Overweight
☐ I don't know

7. How much did you weigh at age 18?

pounds

8. How would you best describe your current principal employment situation?

☐ Employed - Paid Work → a. Are you:
☐ Student
☐ Voluntary or unpaid work
☐ Looking after home and family
☐ Unable to work because of sickness or disability
☐ Unemployed
☐ Retired

b. What age did you retire?

c. Are you currently:
☐ Not employed at all
☐ Employed full-time
☐ Employed part-time

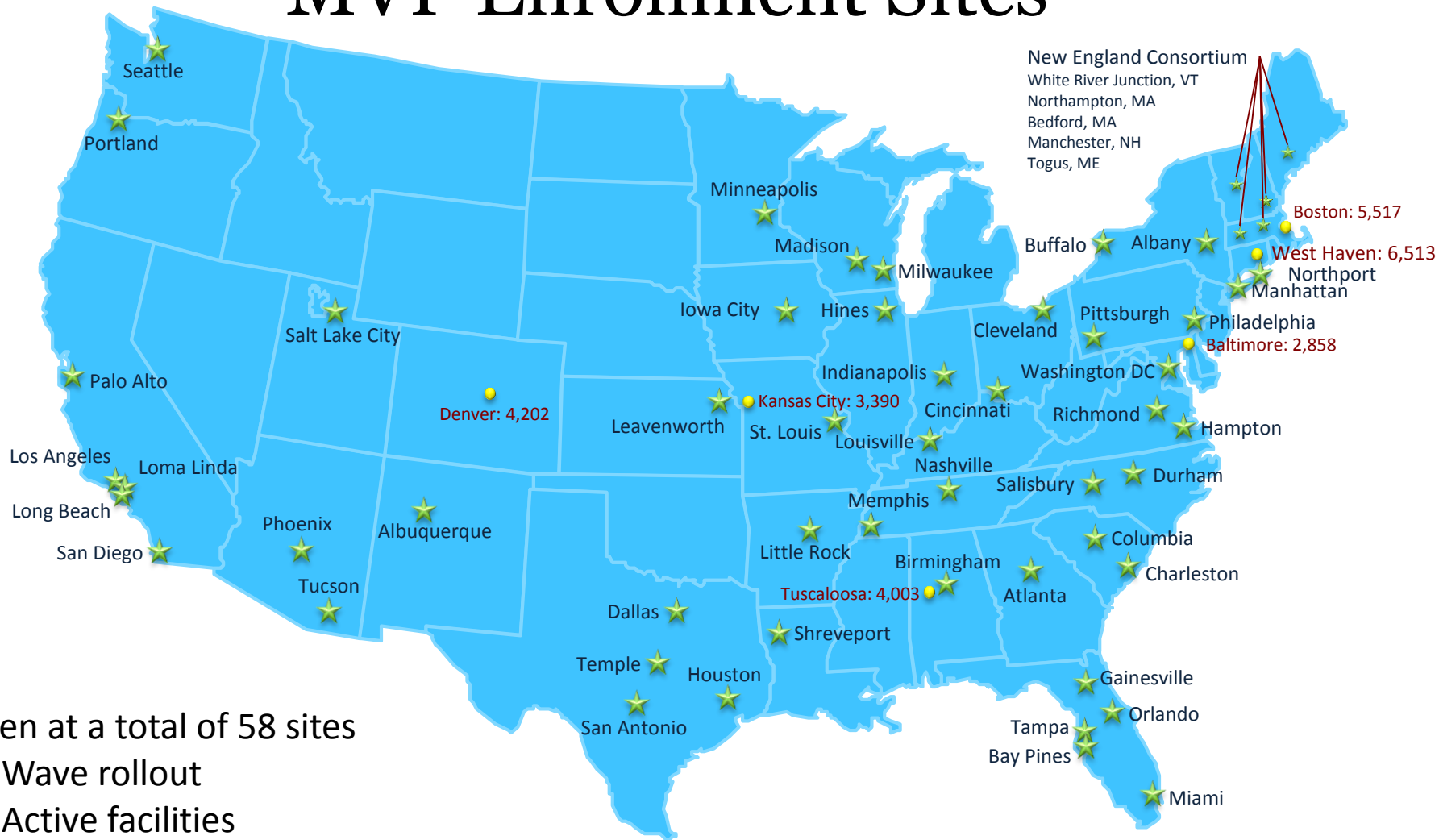
9. Which of the following best describes your working schedule? (Mark all that apply)

☐ Daytime schedule or shift
☐ Evening shift
☐ Night Shift
☐ Rotating shift, changing periodically from days to evenings or nights
☐ Split shift, consisting of two or more distinct periods each day
☐ Compressed work week
☐ On-call or casual, no pre-arranged schedules, but called as need arises
☐ Irregular schedule, usually prearranged one week or more in advance
☐ Seasonal
☐ Other
☐ None, not working

Page 1

GMP LF 04/04/2011

MVP Enrollment Sites



Open at a total of 58 sites

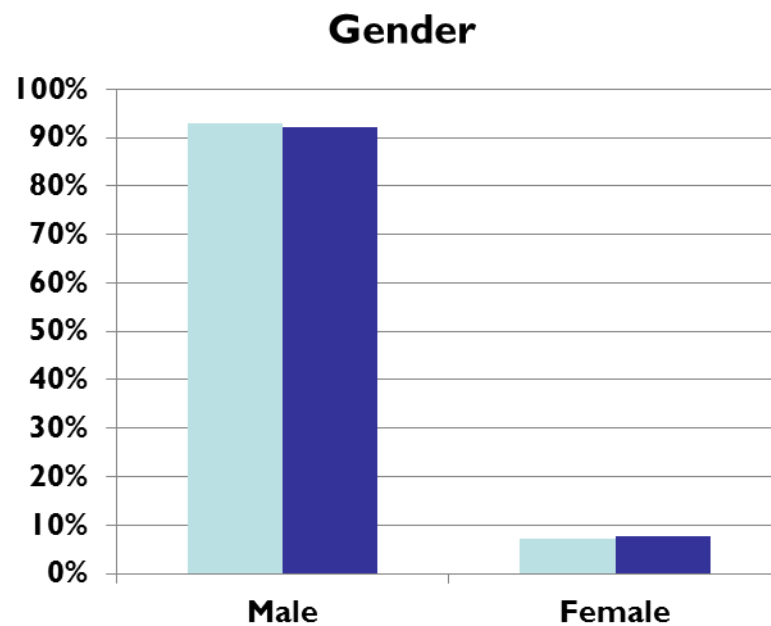
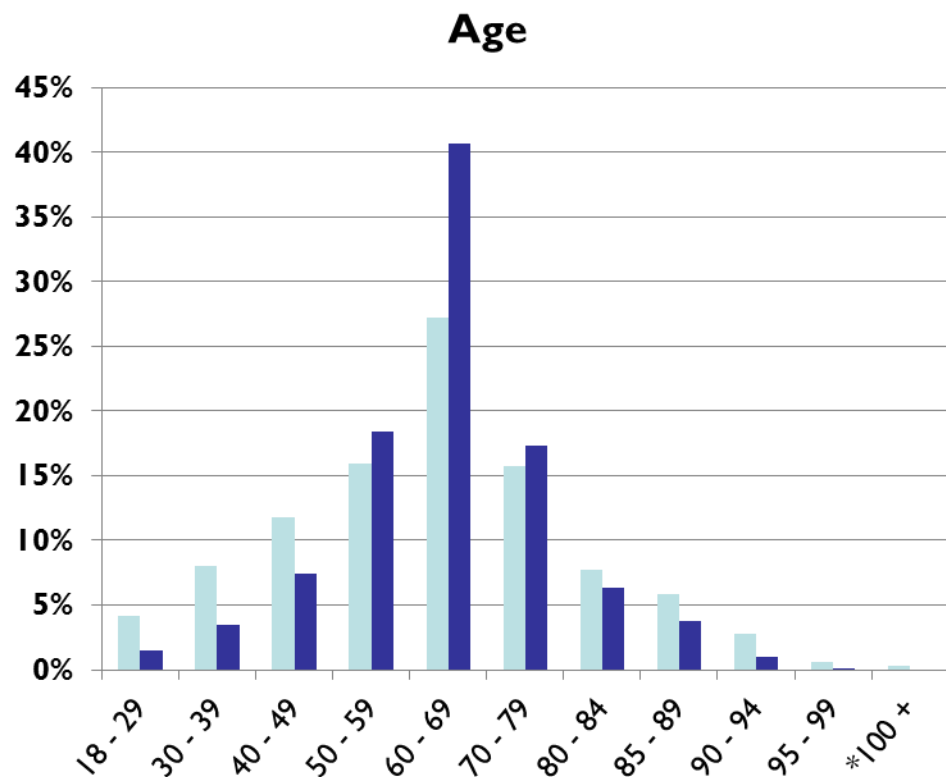
- Wave rollout
- Active facilities
 - 51 main sites
 - 60 satellite facilities
- 5 sites launching in 2016
 - Fayetteville, Muskogee, Providence, Salem, San Francisco

★ = Actively Recruiting
 ● = Closed to Recruitment

MVP Recruitment to Date

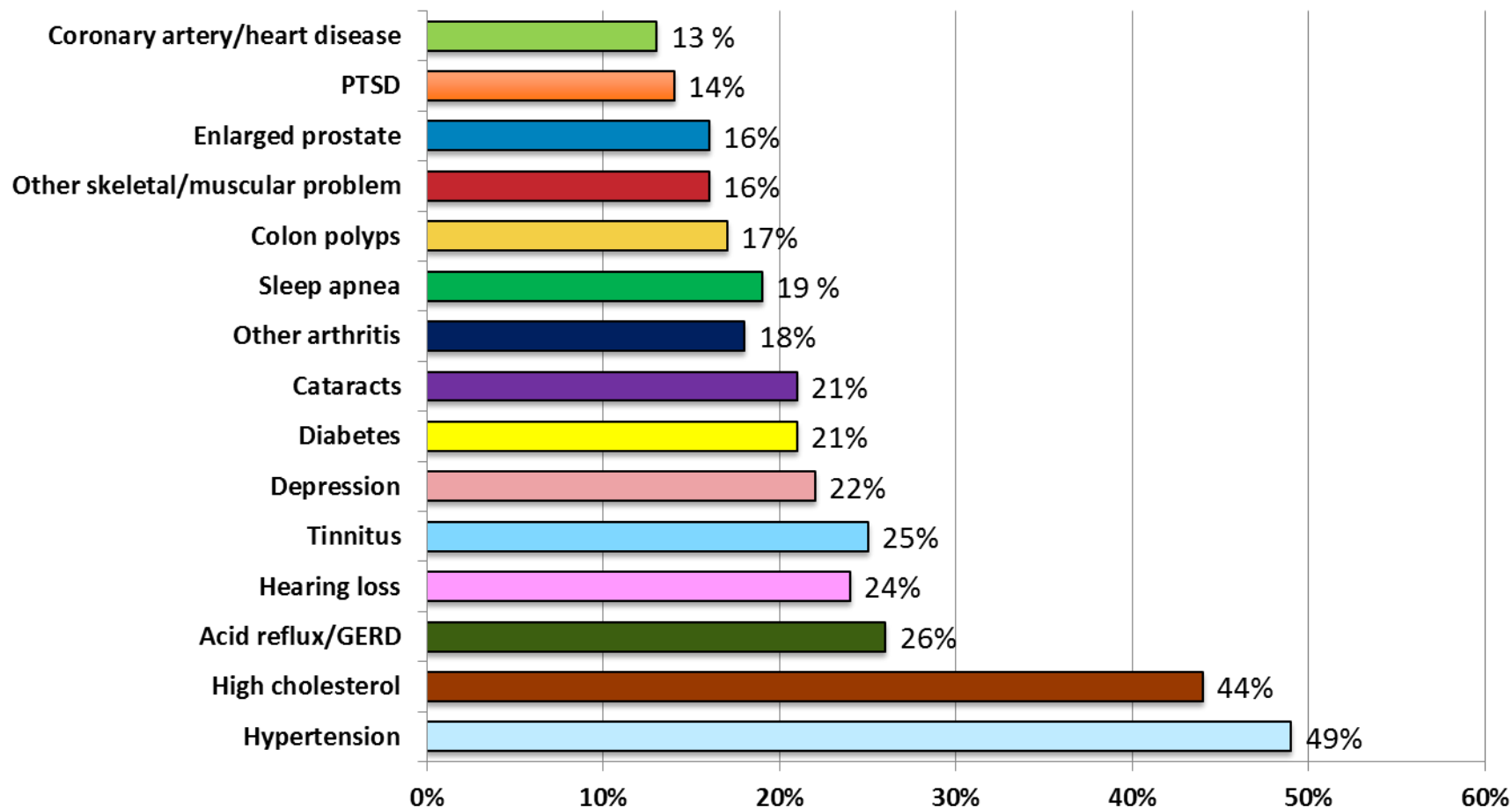
Invitation mailings sent	3.7 Million
Expressed interest by mail	16%
Optout	13%
Completed Baseline Surveys	580,000
Consented Veterans	509,000
Specimens in Lab	506,000
Unscheduled (proportion)	40%
Upcoming appointments	8,000
Call volume	Over 650,000

MVP Enrollees: Age and Gender



■ VHA Population
■ MVP Enrollees
(n=145,270)

MVP Enrollees: Top 15 Self-Reported Diseases and Conditions



n=145,270

Biorepository

- Full service biorepository
- Study planning to analysis
- Develop study specific SOPs
 - Pilot studies
 - Collection kits
 - Trained sites coordinators
 - Process specimens and prepare shipment to analytic laboratory



Specimen Collection

- 4 ice packs must be in the freezer the day before bloods will be drawn
- After obtaining consent, scan barcode on EDTA blood tube to enter blood ID into blood collection form
- Draw blood filling the tube
- Rescan tube
- Refrigerate until shipping



Packing Slip

Shipping Box

Secondary Container
(with absorbent)

Primary Container
(Blood tubes)



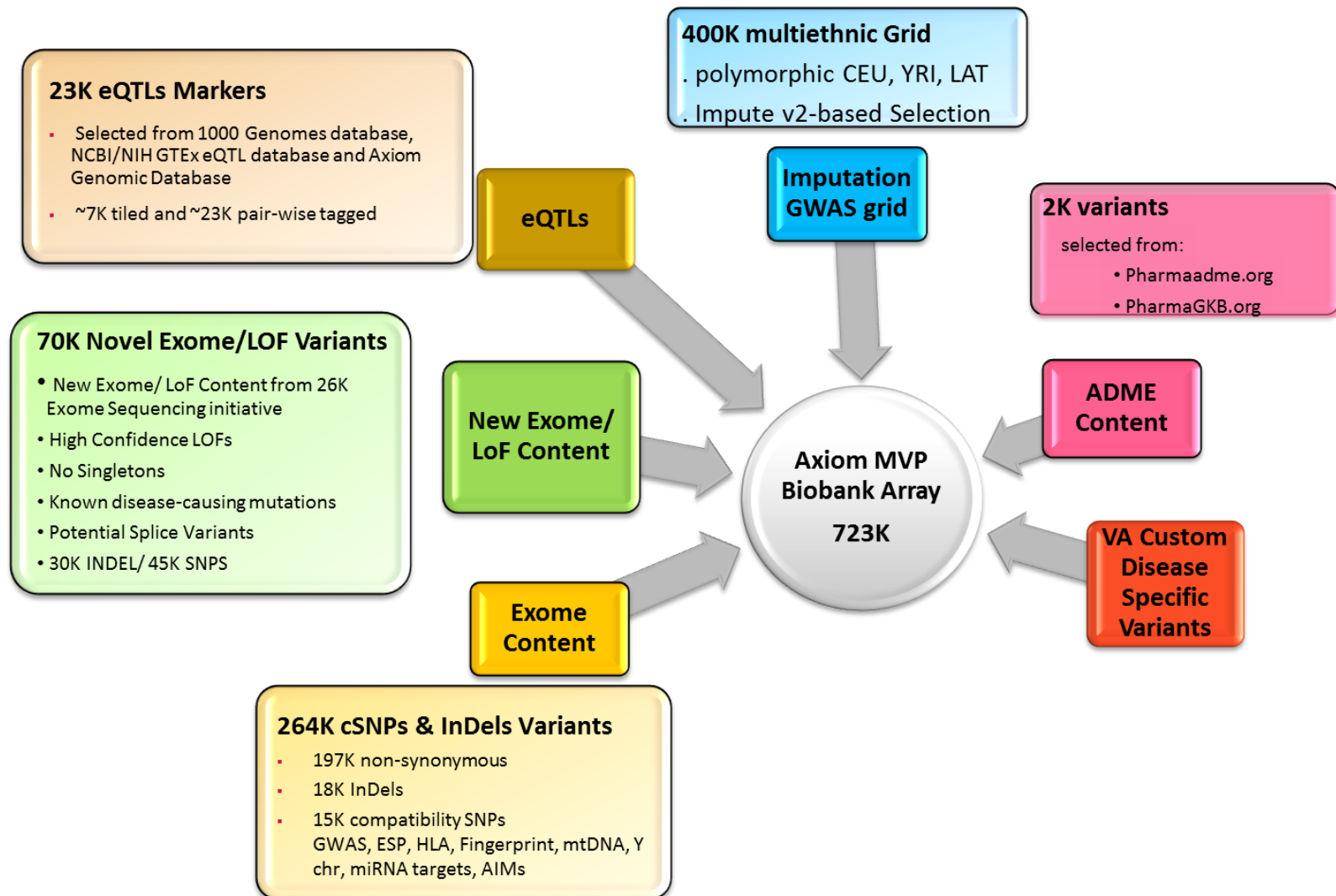




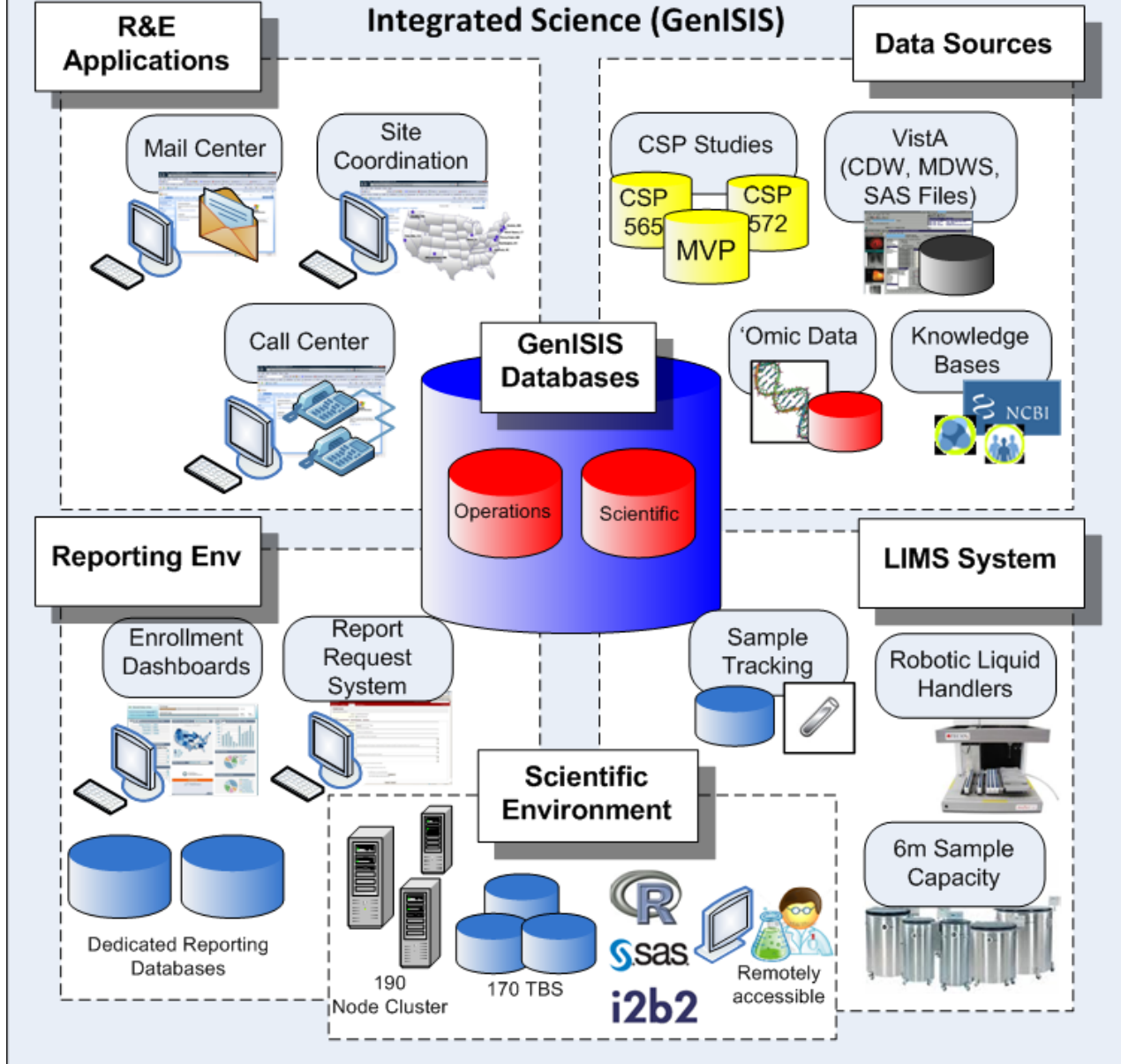
Ongoing Genetic Analyses

- Whole genome sequencing: 2K
 - ALS, Exceptional age
- Whole exome sequencing: 24K
 - Schizophrenia, Bipolar disorder, African Americans
- SNP array (750K SNPs): 500K (2014, 2015, 2016)
 - Randomly chosen from current enrollees

Axiom MVP Biobank Array



The Genomic Information System for Integrated Science (GenISIS)



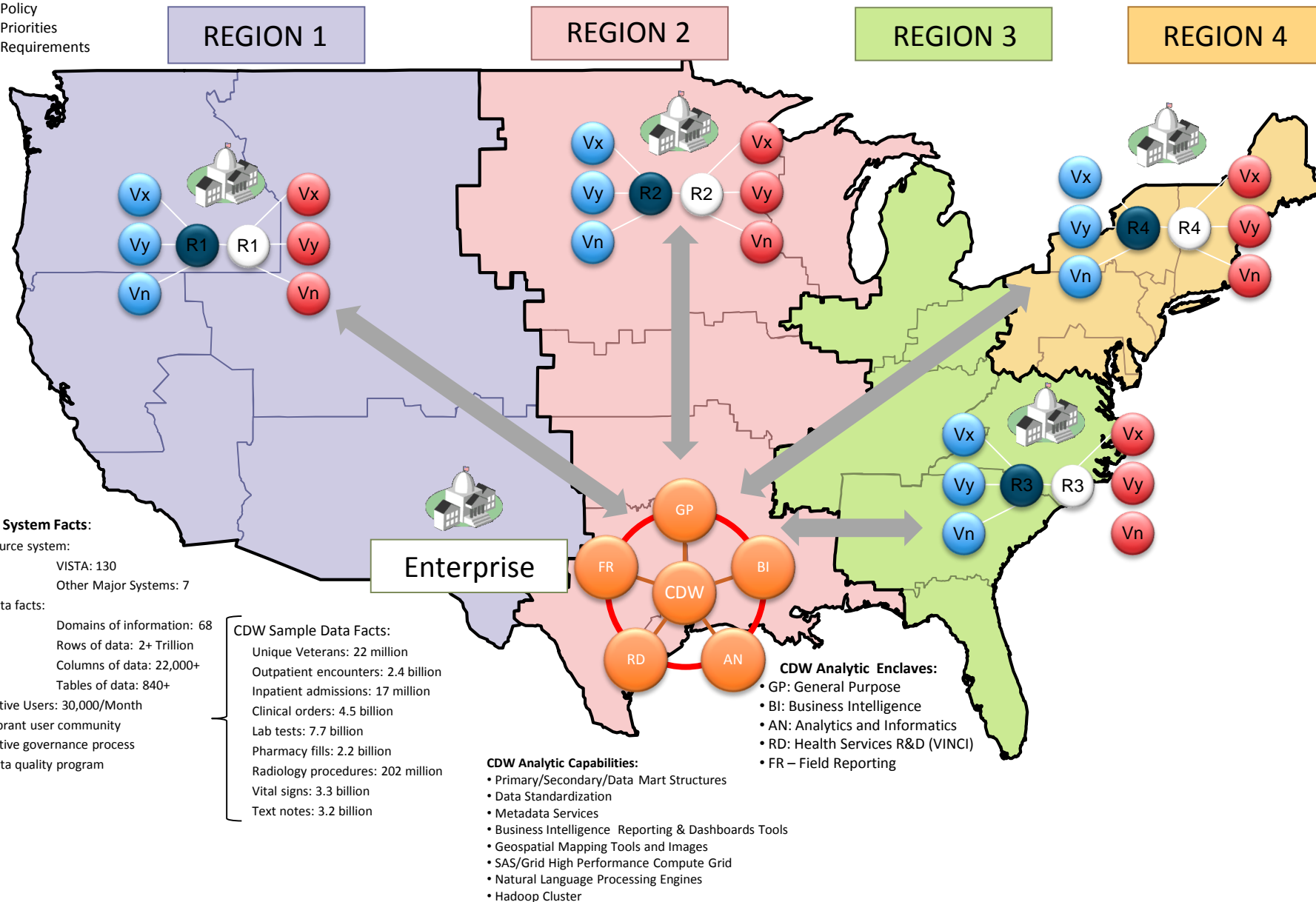


VA Analytic Ecosystem (2015)

Governance Board

- Strategy
- Policy
- Priorities
- Requirements

Common Data ♦ Common Infrastructure ♦ Common Tools ♦ Common Security



Patients: 22 M			
Lab Results 7.7B	Clinical Orders 4.5B	Immunizations 71 M	Appointments 1.4B
Pharmacy Fills 2.2B	Clinical Notes 3.2B	Health Factors 2.2B	Encounters 2.4 B
Radiology Proc 202 M	Vital Signs 3.3B	Consults 315 M	Admissions 17 M

68 Blocks

Surgeries 14 M	Oncology 1.3 M
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The Future: “Big Data”

More and more data is becoming available for health care research: is it a blessing or a curse?

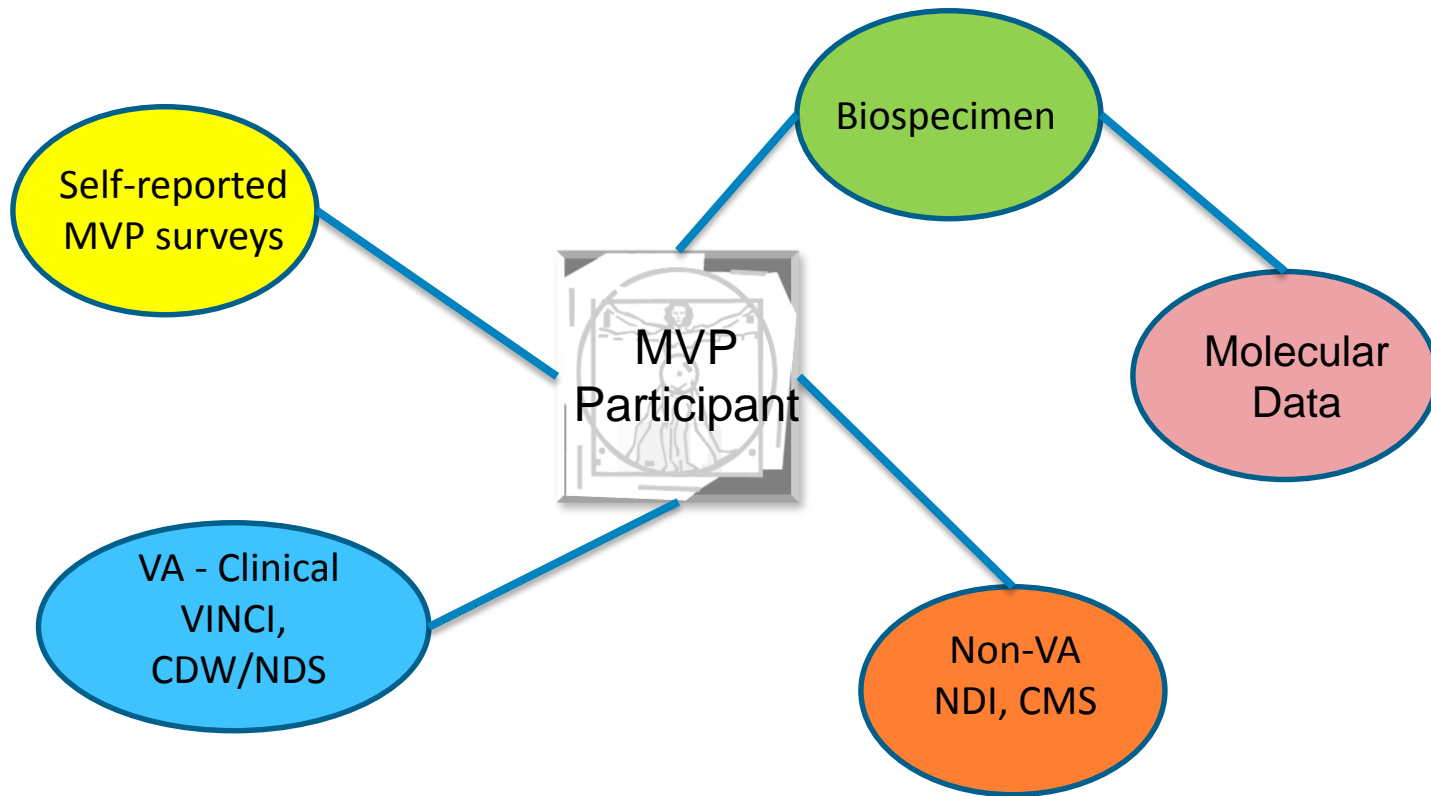
The Future: “Big Data”

More and more data is becoming available for health care research: is it a blessing or a curse?



- *Sometimes, data warehouses resemble landfills more than libraries*
- *Apply the 4 C's: collect, catalogue, clean and curate.*

MVP Data Universe



Data Sources

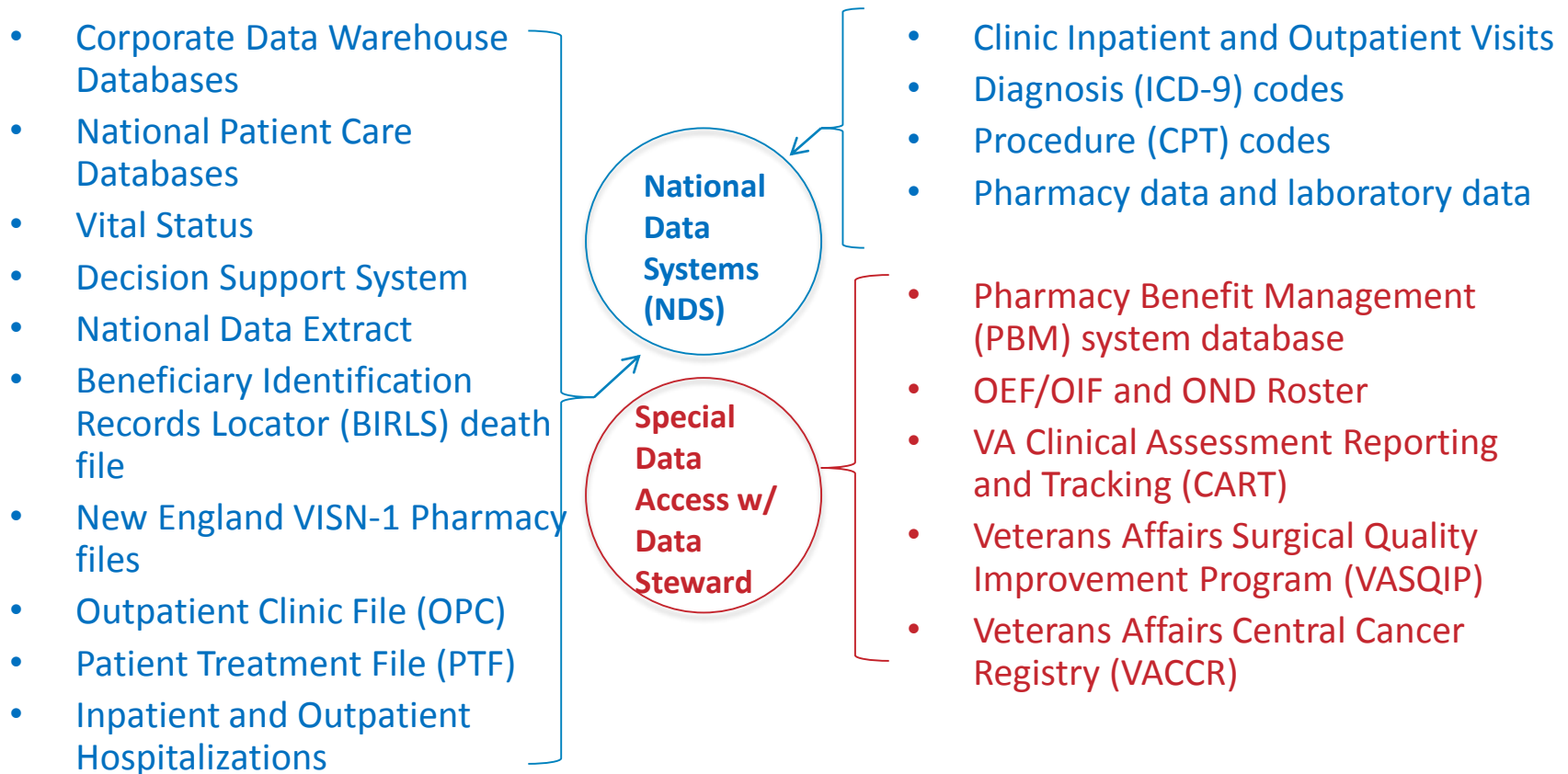
MVP Data

- 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

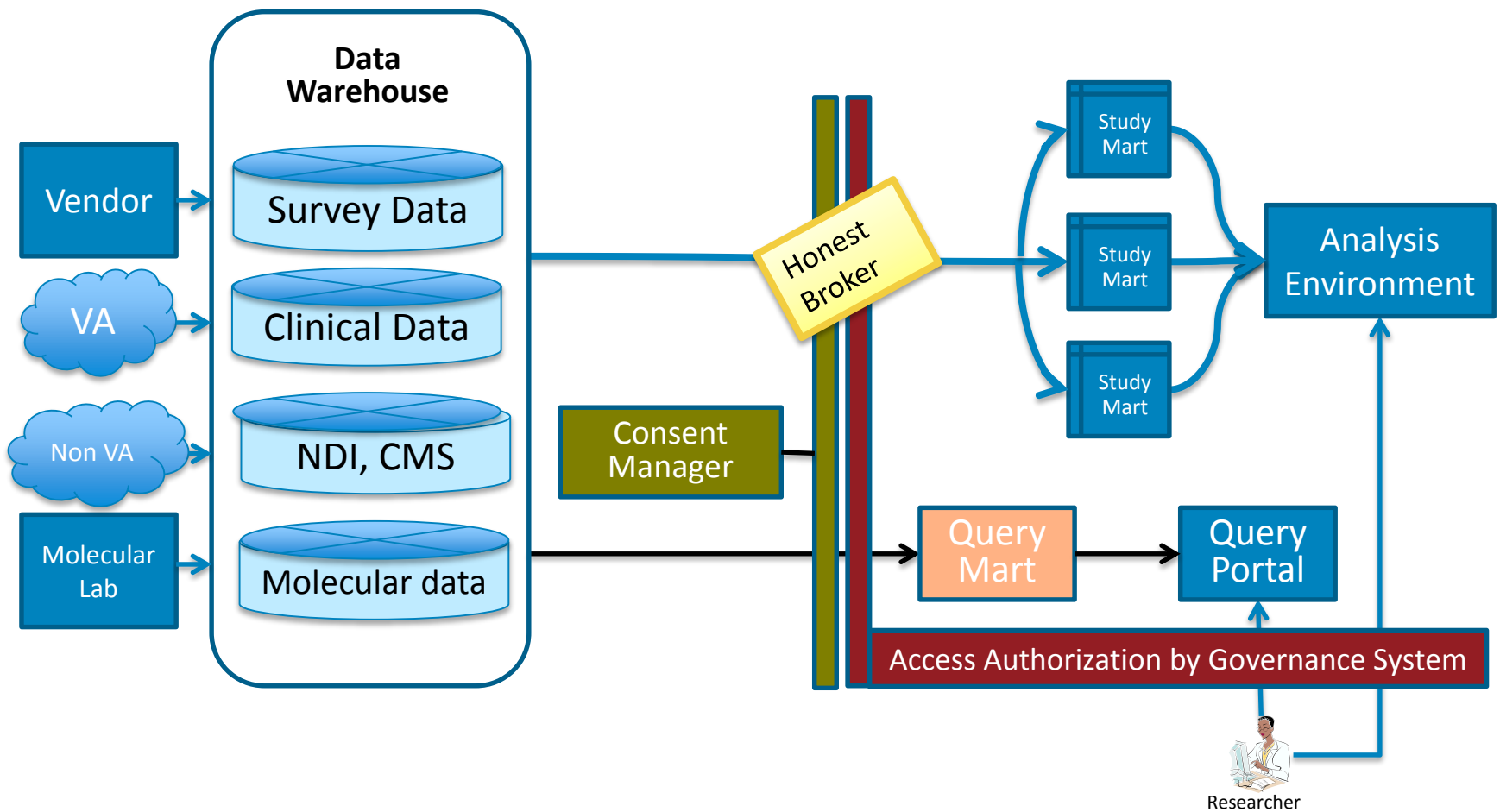
Other Data

- **VA Healthcare System Data**
- **Other Data**
 - National Death Index (NDI)
 - Centers for Medicare and Medicaid Services (CMS)
 - Department of Defense

VA Data Sources



System Architecture



MVP Phenotyping Activities

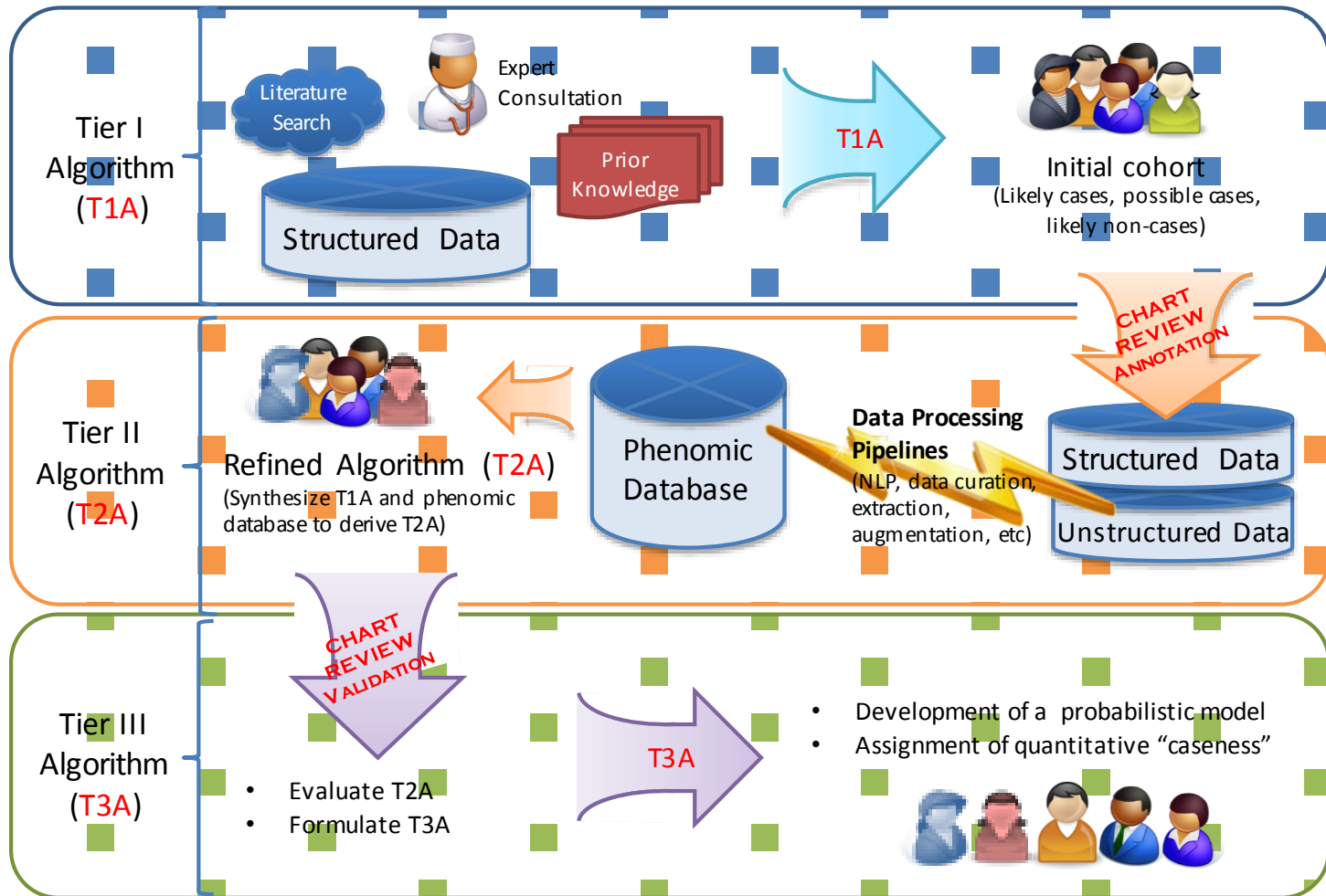
Core Variables

- 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

Complex Phenotypes

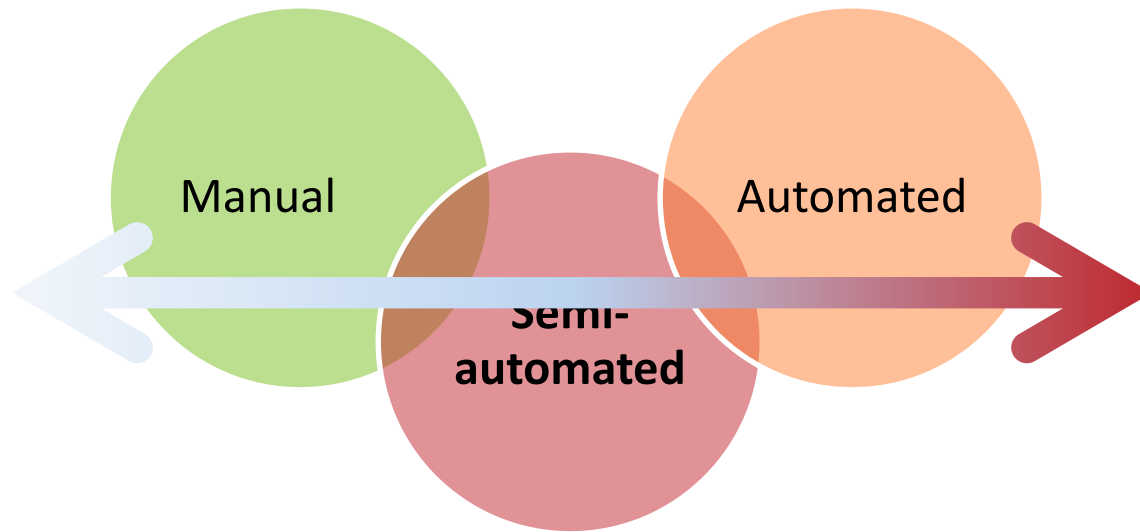
- Disease
 - Myocardial infarction (MI)
 - Stroke
 - Unstable angina with revascularization
 - Acute congestive heart failure
 - Death from cardiovascular disease
 - Vascular procedure
 - Posttraumatic stress disorder (PTSD)
 - Schizophrenia
 - Bipolar disorder
 - Traumatic brain injury
 - Depression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

3-Tier 7-Step Phenotyping Process



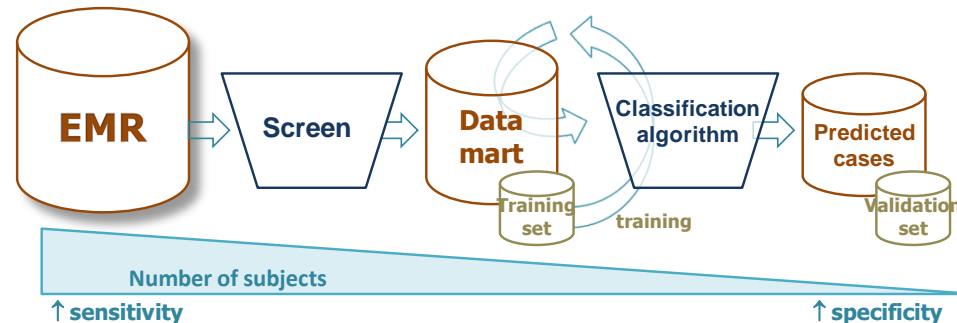
Step 1: Define initial working algorithm (T1A)	Step 5: Derive T2A
Step 2: Create study cohort and apply T1A	Step 6: Evaluate T2A to formulate T3A
Step 3: Create Annotation Data Set	Step 7: Develop probabilistic model and assign caseness
Step 4: Create Phenomic Database through Data Processing Pipelines	Deposit resulting algorithms to a central Phenotype Library

Our Vision for Phenotyping in MVP: A New Approach



Semi-automated phenotyping combines features of manual and automated phenotype development

Overview of semi-automated method for developing EMR phenotypes



Step 1: Create “Phenotype X Mart”

Step 2: Develop gold standard training set

Step 3: Identify variables important for predicting Phenotype X

Codified + narrative data (extracted using natural language processing)

Step 4: Develop algorithm

Logistic regression with LASSO

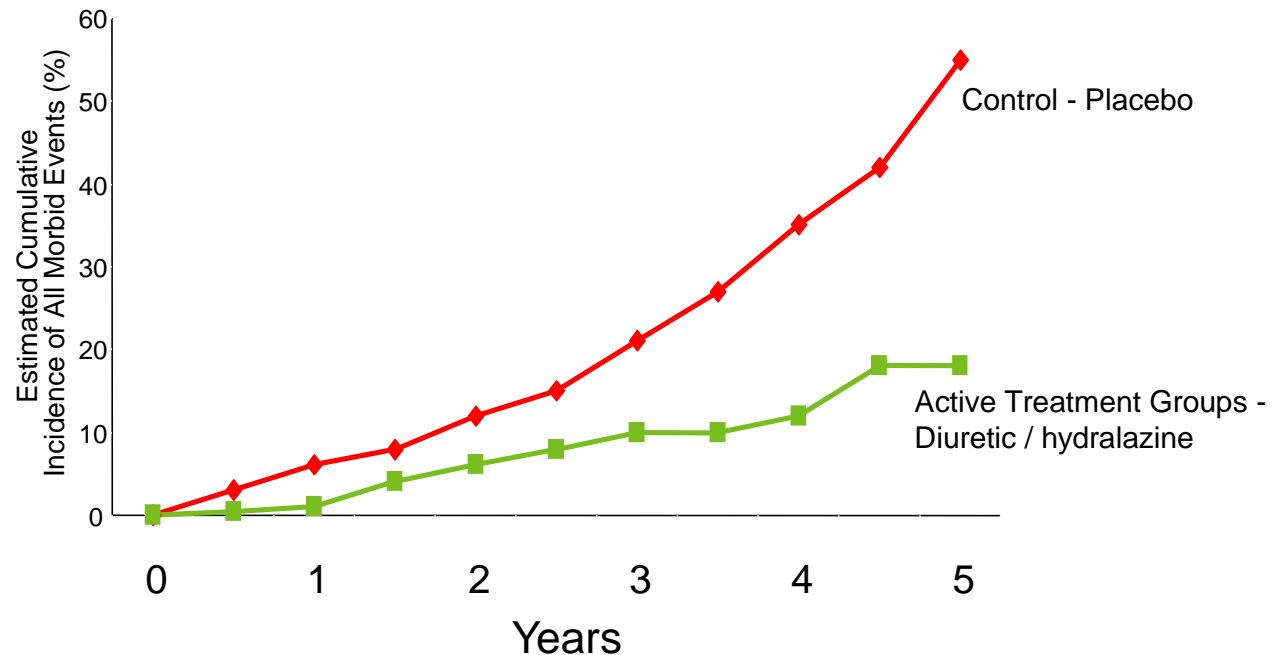
Step 5: Validation

Liao KP, Cai T, Gainer V, et al. Electronic medical records for discovery research in rheumatoid arthritis. Arthritis care & research. Aug 2010;62(8):1120-1127.

Current Projects

- Alpha test
 - Schizophrenia and Bipolar Disorder
 - PTSD
 - Gulf War illness
- Beta test
 - Funding approved for 5 consortia of qualified VA investigators using only MVP Chip genotype data (200K+)
 - Research focus on:
 - Cardiovascular risk factors
 - Cardio-metabolic disorders
 - Kidney disease progression
 - multi-substance use
 - Macular degeneration

Hypertension Treatment Significantly Reduced Mortality and Morbidity in the VA




Veterans Administration Cooperative Study Group on antihypertensive agents *JAMA* 1970;213(7):1143-1152.

Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR

Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

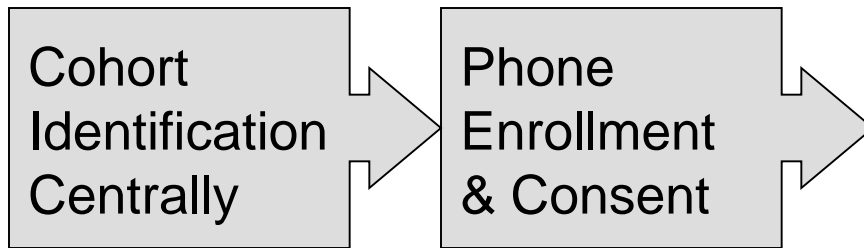
Care providers using EMR



Cohort
Identification
Centrally

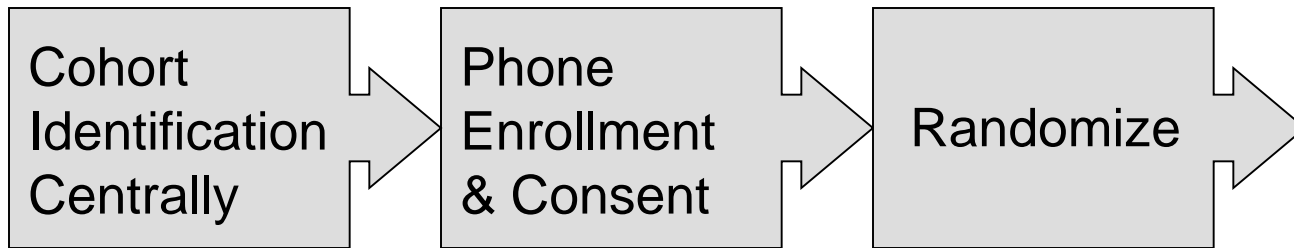
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR



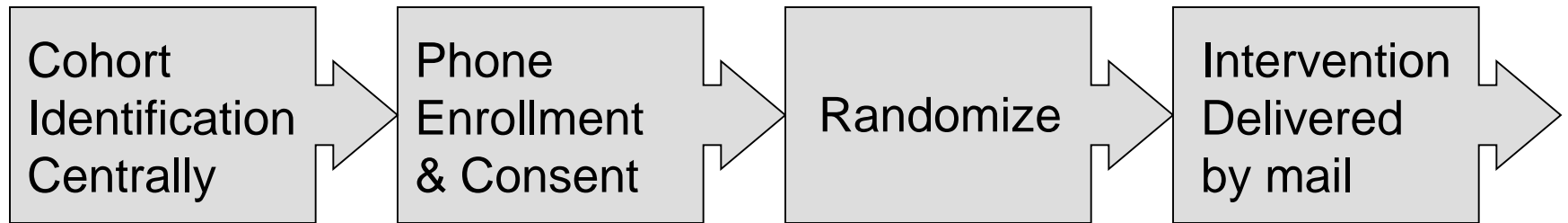
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR



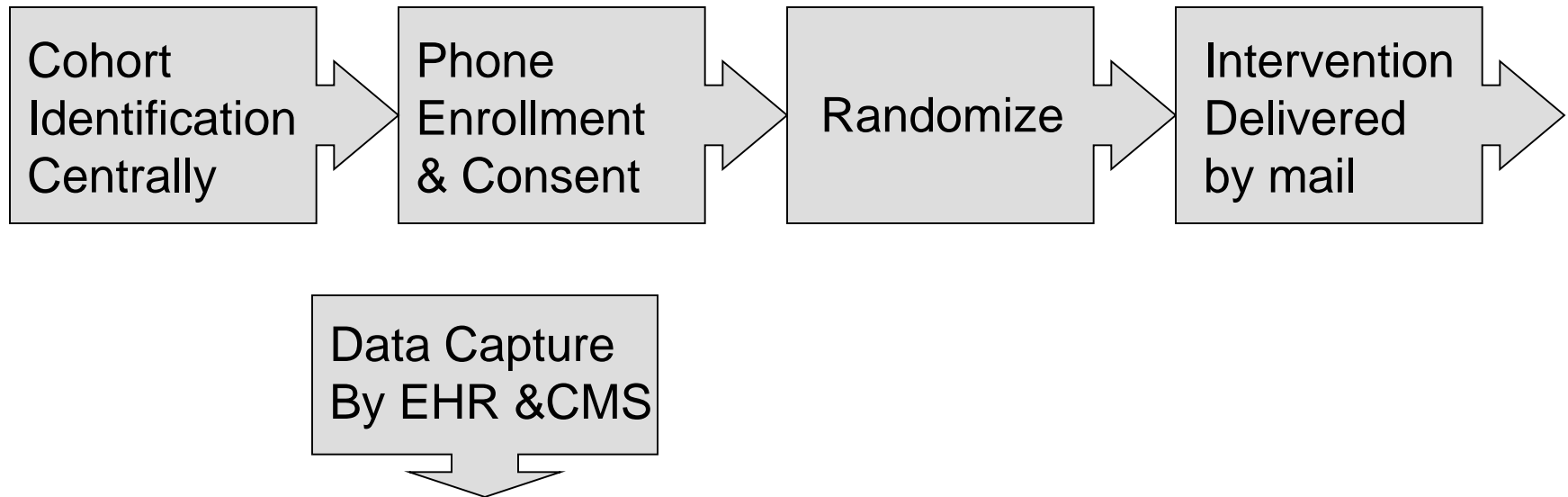
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR



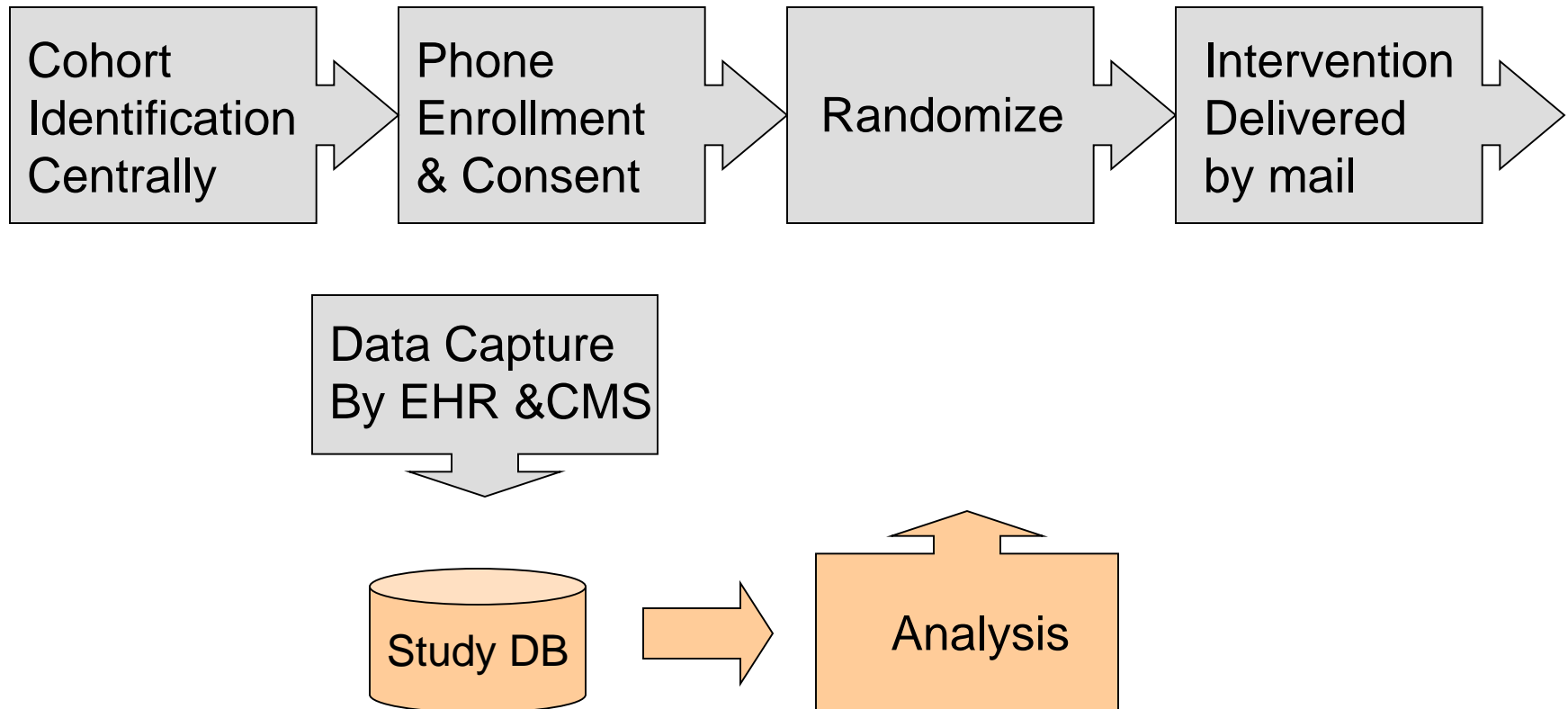
Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR



Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

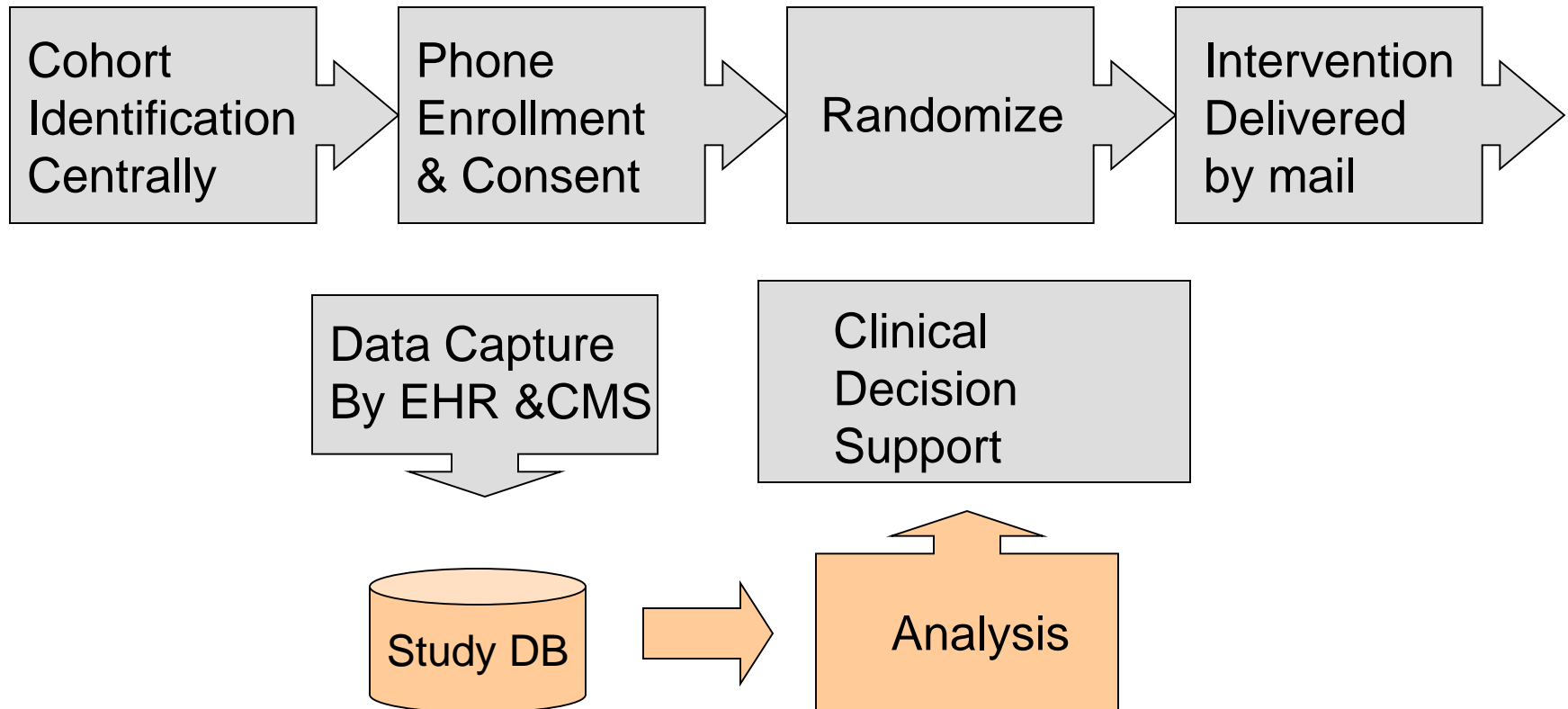
Care providers using EMR



Study team using traditional scientific tools

Pragmatic Trial of HCTZ v. Chlorthalidone at the Point of Care

Care providers using EMR



Study team using traditional scientific tools

Collaboration with PMI-Cohort Program



eMERGE Phenotypes

- ACE Inhibitor (ACE-I) induced cough
- ADHD phenotype algorithm
- Appendicitis
- Atrial Fibrillation
- Autism
- Cardiac Conduction (QRS)
- Cataracts
- Clopidogrel Poor Metabolizers
- Crohn's Disease
- Dementia
- Diabetic Retinopathy
- Drug Induced Liver Injury
- Heart Failure
- Height
- Herpes Zoster
- HDL
- Hypothyroidism
- Fibromyalgia in an RA cohort
- Lipids
- MidSouth CDRN CHD Algorithm
- Multiple Sclerosis
- Peripheral Arterial Disease
- Red Blood Cell Indices
- Rheumatoid Arthritis
- Severe Early Childhood Obesity
- Sleep Apnea Phenotype
- Type 2 Diabetes – 2 phenotypes
- Warfarin dose/response
- White Blood Cell Indices

CHARGE Consortium Working Groups

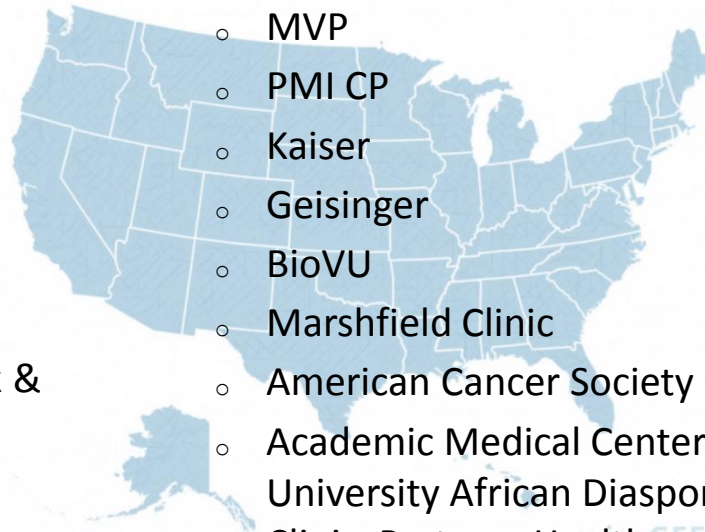
• Adiposity	• Hemostasis
• Atrial Fibrillation/PR-Interval	• Inflammation
• Aging and Longevity	• Insulin Like Growth Factor
• Blood Pressure	• Lipids
• CHARGE-S Analysis & Bioinformatics	• Microbiome
• CHARGE mtDNA+	• Musculoskeletal
• Depression	• Natriuretic Peptides
• Echocardiography: EchoGen	• Neurology (specific subgroups on Stroke, Dementia...)
• Educational Attainment	• Nutrition
• EKG	• Pharmacogenetics
• Endothelial Function	• Physical Activity
• Entrepreneurship	• Pulmonary
• Epigenetics	• Renal
• Exome Chip	• Repro-GEN
• Eye Retina	• Sex Hormone
• Family Studies	• Sleep
• Fatty Acid	• Subclinical / CHD
• Gene Expression	• Sudden Cardiac Arrest
• Gene-Lifestyle Interactions	• Telomeres
• Glycemia/Diabetes	• Thyroid Function
• Hearing loss	• Tonometry
• Heart Failure	• Venous Thromboembolism
• Hematology	

Large-Scale Biobanks

Europe

- UK Biobank
- Icelandic Biobank
- Banco Nacional de ADN
- GenomEUtwin
- Finnish biobank
- Swedish biobank
- German biobank, KORA
- UK DNA Banking Network & British biobank
- Estonian biobank
- Generation Scotland
- HUNT (cardiovascular) & Biohealth
- EPIC, European (cancer)
- Danubian Biobank Consortium
- GATiB Genome Austria Tissue Bank
- Biobank Hungary

United States



- MVP
- PMI CP
- Kaiser
- Geisinger
- BioVU
- Marshfield Clinic
- American Cancer Society
- Academic Medical Centers: Howard University African Diaspora, Mayo Clinic, Partners Healthcare, Chicago area consortium, etc.
- Health system consortia: eMERGE
- Large scale cohorts in consortia: CHARGE, NCI Cancer Cohort Consortium

International

- Kadoorie (China)
- Mexico City
- Gambian National DNA Bank (Africa)
- H3 Africa
- KHCCBIO (Jordan)

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U.S. Marine Corps

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VA Connecticut Healthcare System



“I have always known someone in the family with Diabetes or Hypertension. I eagerly volunteered to participate in MVP so I can help medical researchers better understand how genes influence diseases. One blood draw is all it took... yet the potential to contribute to scientific discoveries is enormous!”

Priscilla Bryant

U.S. Army

1974 - 1994

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“Knowing that I would be helping other GI’s is the reason I am part of the Million Veteran Program.”

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“With malice toward none, with charity for all, with firmness in the right as God gives us to see the right, let us strive on to finish the work we are in, to bind up the nation’s wounds, to care for him who shall have borne the battle and for his widow, and his orphan, to do all which may achieve and cherish a just and lasting peace among ourselves and with all nations.” *Lincoln, March, 1865*

Thank You!



Thank You!