NIH Collaboratory

Health Care Systems Research Collaboratory

The NIH Collaboratory Distributed Research Network

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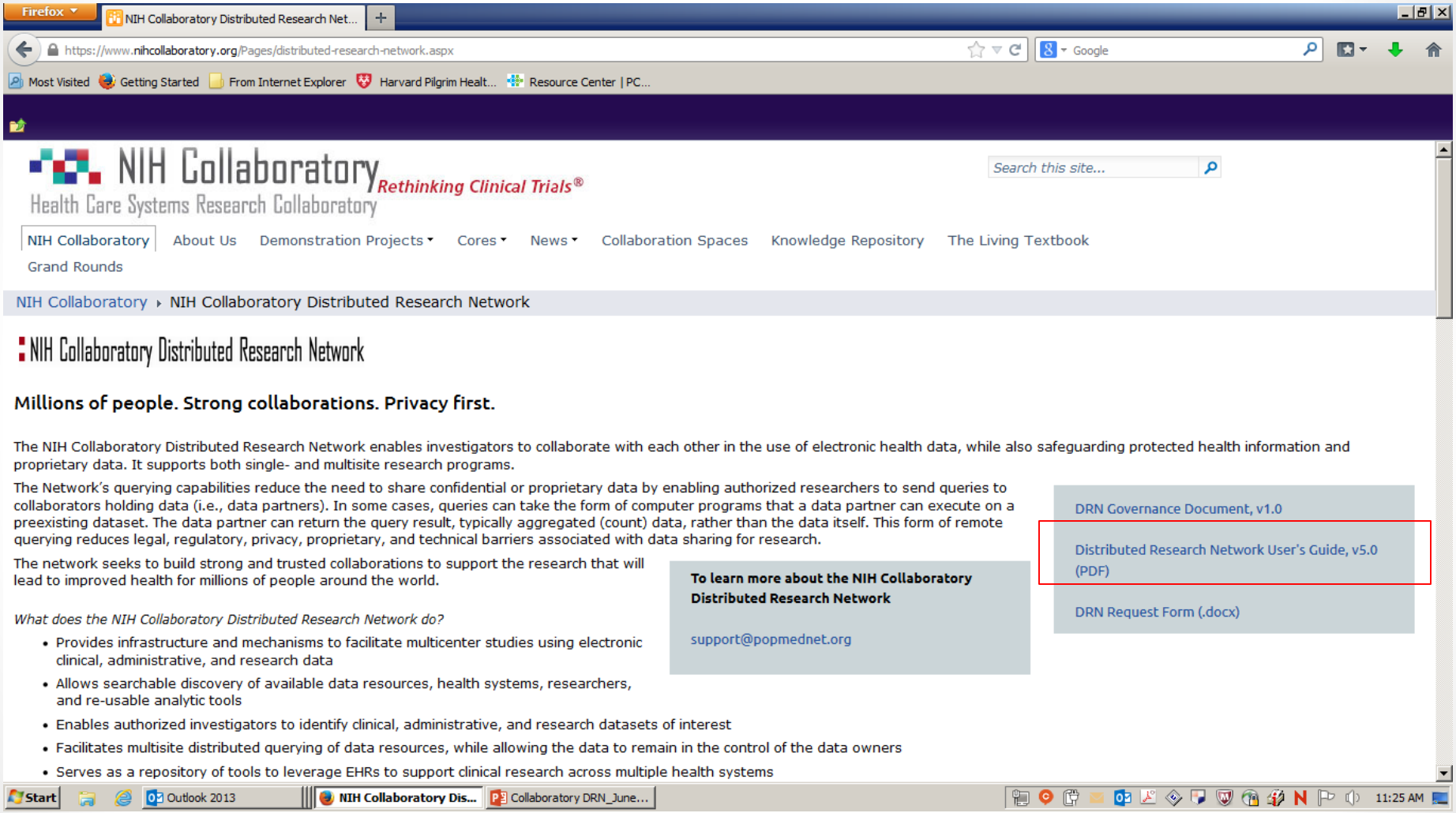
The Goal

The NIH Collaboratory DRN facilitates research partnerships with organizations (Data Partners) that possess **electronic health data that have been quality checked and formatted** to support multi-site biomedical research

https://www.nihcollaboratory.org/Pages/distributed-research-network.aspx



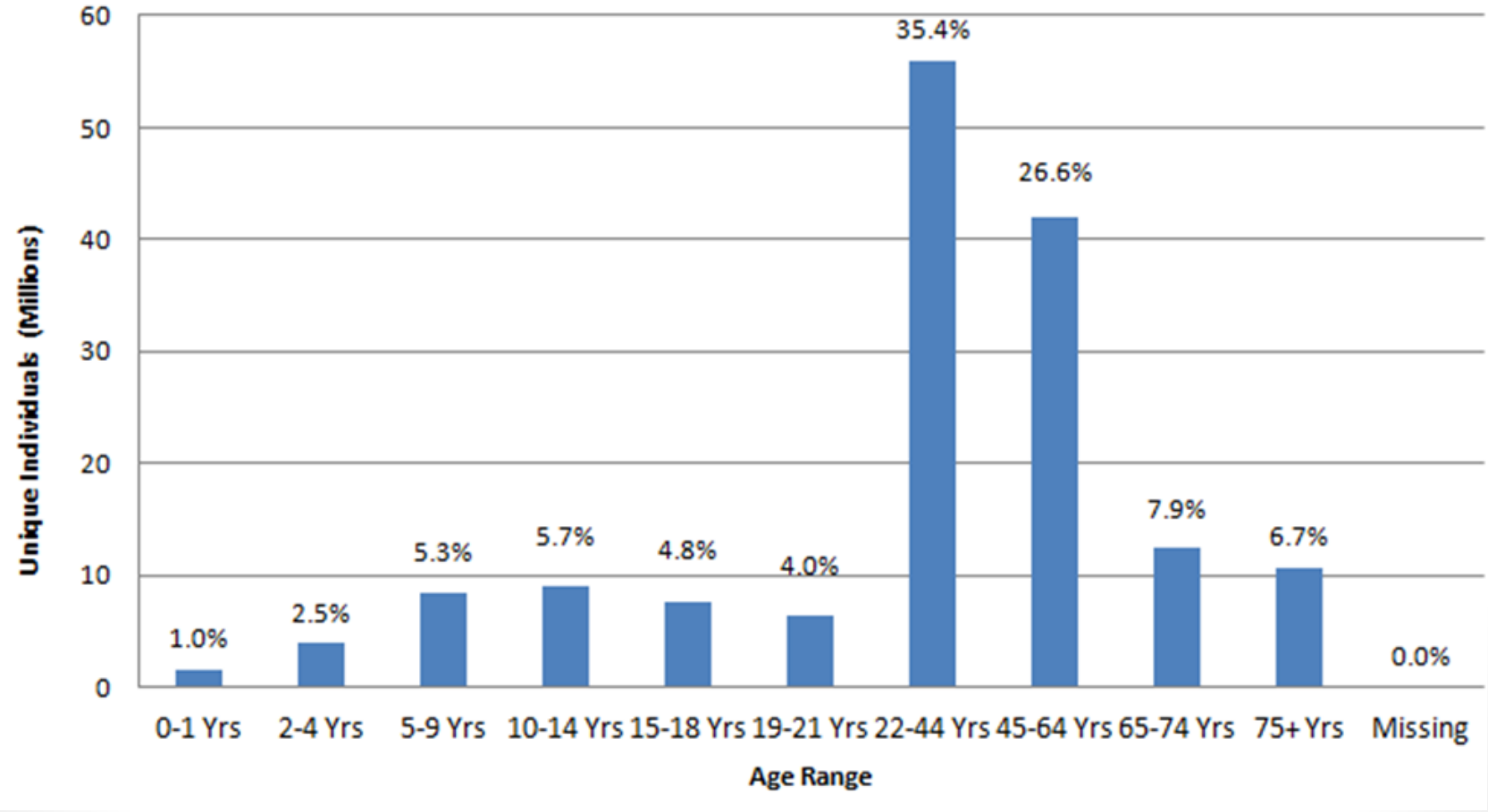
Uses of the Distributed Network

- Provide information to support research planning
  - Background rates
  - Assess assumptions about relevant populations
  - Prioritize research domains
- Answer specific research questions
- Identify sites for participation in prospective interventional or observational studies

Currently Available Data

- Research ready data sets representing >90% of the FDA Sentinel program
- > 300 million person-years of observation time and detailed information for billions of medical encounters and outpatient pharmacy dispensings

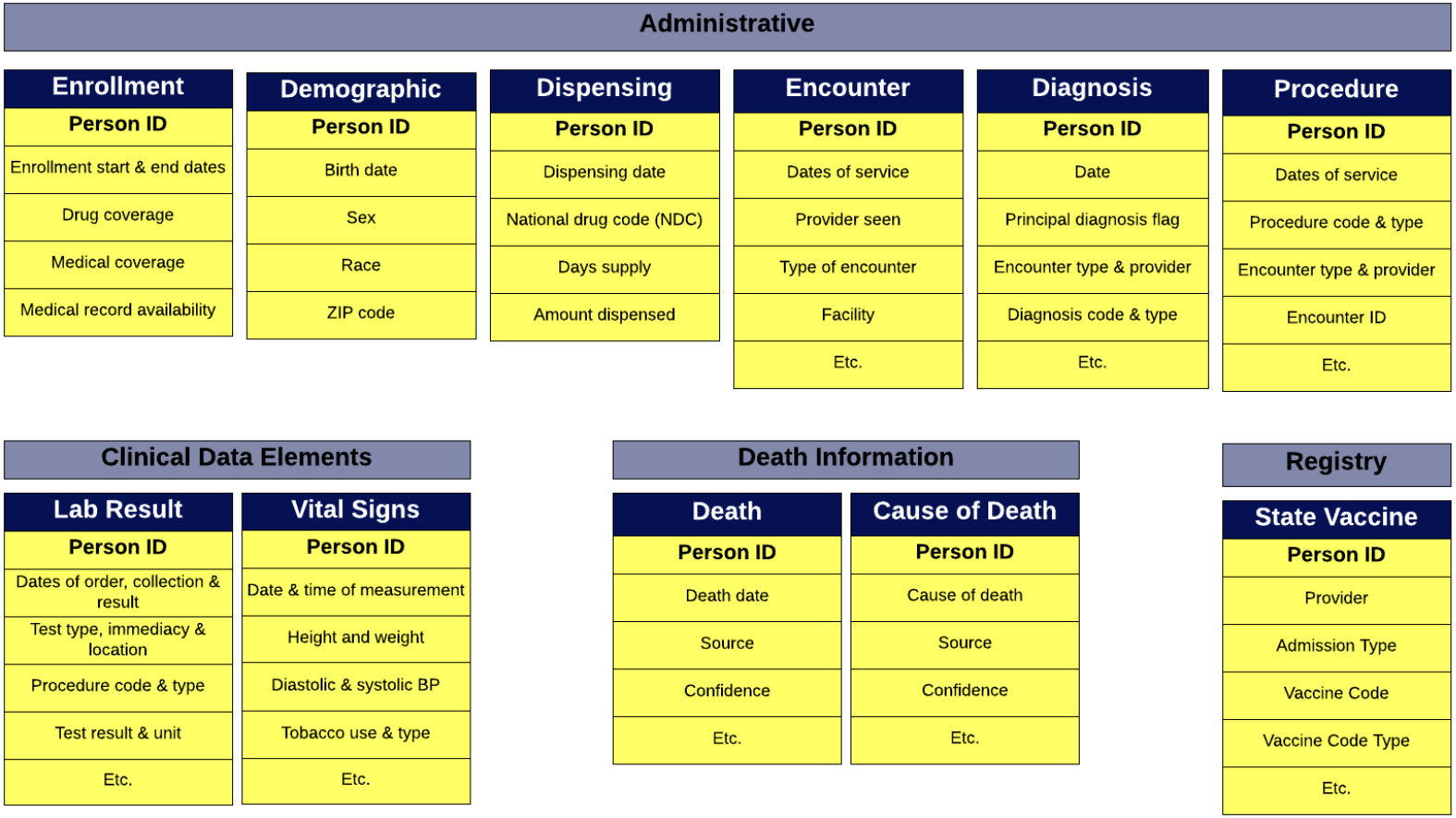
Unique Individuals by Age Range



Data Elements

- Captured
  - Ambulatory care diagnoses and procedures
  - Outpatient pharmacy dispensing
  - Laboratory testing and selected test results
  - Inpatient diagnoses, treatments and procedures itemized in hospital bill
- Not captured
  - Out of hospital death
  - Over-the-counter medication
  - Community-based immunizations

Data Model



Some data partners do not create every table
(e.g., vital signs are available for only a subset of individuals)

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  - Counts, exposure-outcome relationships, confounder adjusted comparative cohort analyses

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  - Data exists but completeness and quality must be determined

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- Harder: New data is needed
  - Birth registry, death registry, etc

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- Harder: New data is needed
  - Birth registry, death registry, etc
- Impossible: The data isn't reliably captured
  - Race, smoking status, over the counter medication use

Where does the question fall on the continuum

- The DRN Coordinating Center helps requesters or their designees understand and use the network
- Assess fit between requests and the DRN's capabilities
- Suggest ways to maximize usefulness of the DRN data resources
- Facilitate engagement with data partners
- **Requesters do not have to be experts in observational research or use of health care data to initiate a request**

Easy Example: Simple Counts

- Query goals
  - Counts of patients with Progressive Multifocal Leukoencephalopathy (PML)
- Analysis
  - Number of patients and prevalence rate of PML identified in inpatient setting
  - Counts provided per patient per year, age group, and sex

Easy Example: Simple Counts

Result: In 2012, there were 87 individuals identified

Prevalence of Progressive Multifocal Leukoencephalopathy in 2012				
Age (years)	Males	Prevalence per 10,000	Females	Prevalence per 10,000
0-21	1	0.01	0	0
22-44	16	0.14	8	0.07
45-64	29	0.31	18	0.18
65+	6	0.16	9	0.20

Easy Example: Cohort Identification and Descriptive Analysis

- Query goals
  - Patients continuously exposed to **bisphosphonates** for ≥3 years
  - Assess the risk of hip and other fractures
- Analysis
  - 2006 - 2013
  - Health plan members with medical and pharmacy coverage
  - **New** users of alendronate, risedronate, & ibandronate
  - Create treatment episodes based on repeated exposures
  - Identify fractures during or shortly after treatment
  - Sensitivity analyses examined different exposure, event, and episode definitions (n=78 analyses)

Easy Example: Cohort Identification and Descriptive Analysis

Results

- ~34,000 new users
- ~22,000 current alendronate users exposed for 3 - 5 years
- ~9,000 people enter this cohort each year

Fractures in long term alendronate users*				
Fracture type	**Exposed people**	**Person time (yrs)**	**Fractures**	**Rate / 10K yrs**
Hip	34,428	138,386	725	52
Femoral fractures of interest	34,672	140,020	339	24

* New users of alendronate, continuously exposed for at least 3 years

Easy Example: Propensity score matched comparison

- Query goals
  - What is the comparative risk of angioedema among new users of ACE inhibitors vs. new users of beta-blockers?
- Analysis
  - Propensity score matched survival analysis
  - Performed via reusable modular program requiring only specification of input parameters

www.mini-sentinel.org/work_products/Statistical_Methods/Mini-Sentinel_Methods_Known-Positives-ACEI-Angioedema.pdf

Easy Example: Propensity score matched comparison

Input parameters

- Population (age/sex/etc.), time period
- Exposures
- Outcomes
  - ICD-9-CM code 995.1 in any position during outpatient, inpatient, or emergency department encounter
  - Washout period (days before first dispensing): 183 days
- Inclusion criteria
- Exclusion criteria
- Covariates
- Propensity score matching options
  - Comorbidity, utilization, high dimensional propensity score
  - Matching ratio
  - Caliper size

Angioedema: Table 1. Unmatched Cohort

Table 1. Cohort of New Initiators of ACE Inhibitors and Beta Blockers (Unmatched)

	Primary Analysis				Covariate Balance	
Characteristic	**ACE Inhibitors**		**Beta Blockers**			
	N	**%**	**N**	**%**	**Absolute Difference**	**Standardized Difference**
Patients	2,211,215	100%	1,673,682	100%	0.0	-
Events while on therapy	5,158	0.2%	1,292	0.1%	0.1	0.0
Person-time at risk (days)	186.9	266.6	149.2	235.1	37.7	0.2
Patient Characteristics						
Gender (F)	997,962	45.10%	946,344	56.50%	-11.4	-0.2
Mean age (std dev)	54.6	12.7	53.7	15.6	0.9	0.1
Recorded History of:						
Allergic reactions	207,344	9.4%	190,387	11.4%	-2.0	-0.1
Diabetes	471,661	21.3%	173,083	10.3%	11.0	0.3
Heart failure	41,060	1.9%	74,897	4.5%	-2.6	-0.1
Ischemic heart diseases	109,948	5.0%	224,681	13.4%	-8.4	-0.3
NSAID use	318,298	14.4%	250,697	15.0%	-0.6	0.0
Health Service Utilization Intensity:	**Mean**	**Std Dev**	**Mean**	**Std Dev**		
Number of generics	3.4	3.5	4.1	4.0	-0.7	-0.2
Number of filled prescriptions	7.5	9.6	8.9	10.8	-1.4	-0.1
Number of inpatient hospital encounters (IP)	0.1	0.4	0.2	0.6	-0.1	-0.3
Number of non-acute institutional encounters (IS)	0.0	0.6	0.1	0.9	-0.1	-0.1
Number of emergency room encounters (ED)	0.2	0.7	0.4	1.0	-0.2	-0.2
Number of ambulatory encounters (AV)	4.8	6.3	6.9	8.4	-2.1	-0.3
Number of other ambulatory encounters (OA)	1.1	2.6	1.5	3.6	-0.4	-0.1

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3.9 million new users

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Ischemic heart diseases	109,948	5.0%	224,681	13.4%	-8.4	-0.3
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Health Service Utilization Intensity:	**Mean**	**Std D[illegible]**				
Number of generics	3.4	3.5				
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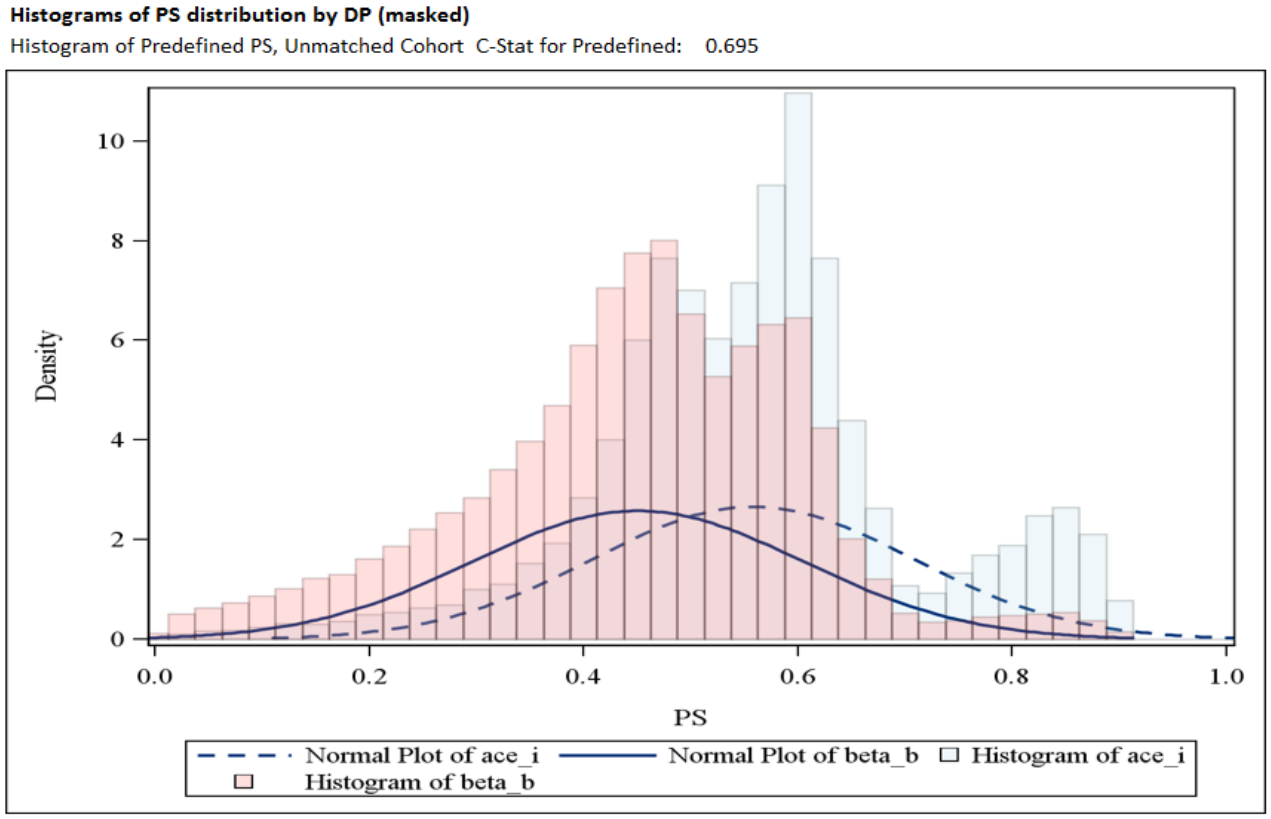
3.9 million new users

Diabetes 21% vs 10%
Heart failure 2% vs 4%
Ischemic heart disease 5% vs 13%

www.mini-sentinel.org/work_products/Statistical_Methods/Mini-Sentinel_Methods_Known-Positives-ACEI-Angioedema.pdf

Propensity Scores Before Match



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Angioedema: Table 2. Matched Cohort

Table 2. Cohort of New Initiators of ACE Inhibitors and Beta Blockers (Matched Predefined PS, Caliper = .025)

	Primary Analysis				Covariate Balance	
	ACE Inhibitors		Beta Blockers			
	N	%	N	%	Absolute Difference	Standardized Difference
Patients	1,309,104	59.2%	1,309,104	78.2%	0.0	-0.4
Events while on therapy	3,311	0.3%	988	0.1%	0.2	0.0
Person-time at risk (days)	183.8	263.7	151.8	238.9	31.9	0.1
Patient Characteristics						
Gender (F)	723,955	55.3%	689,617	52.7%	2.6	0.1
Mean age (std dev)	54.1	13.1	54.4	14.9	-0.3	0.0
Recorded History of:						
Allergic reactions	137,920	10.5%	134,933	10.3%	0.2	0.0
Diabetes	150,036	11.5%	150,551	11.5%	0.0	0.0
Heart failure	35,302	2.7%	38,966	3.0%	-0.3	0.0
Ischemic heart diseases	102,200	7.8%	106,786	8.2%	-0.4	0.0
NSAID use	191,798	[illegible]7%	189,612	14.5%	0.2	0.0
Health Service Utilization Intensity:	Mean	Sto[illegible]				
Number of generics	3.7	3.7%				
Number of filled prescriptions	8.1	10.2%				
Number of inpatient hospital encounters (IP)	0.1	0.5%				
Number of non-acute institutional encounters (IS)	0.1	0.7%	0.1	0.7%	0.0	0.0
Number of emergency room encounters (ED)	0.3	0.8%	0.3	0.8%	0.0	0.0
Number of ambulatory encounters (AV)	5.6	7.3%	5.6	6.6%	0.0	0.0
Number of other ambulatory encounters (OA)	1.2	2.9%	1.3	3.0%	0.0	0.0

2.6 million new users

Diabetes 10% vs 10%
Heart failure 3% vs 3%
Ischemic heart disease 8% vs 8%

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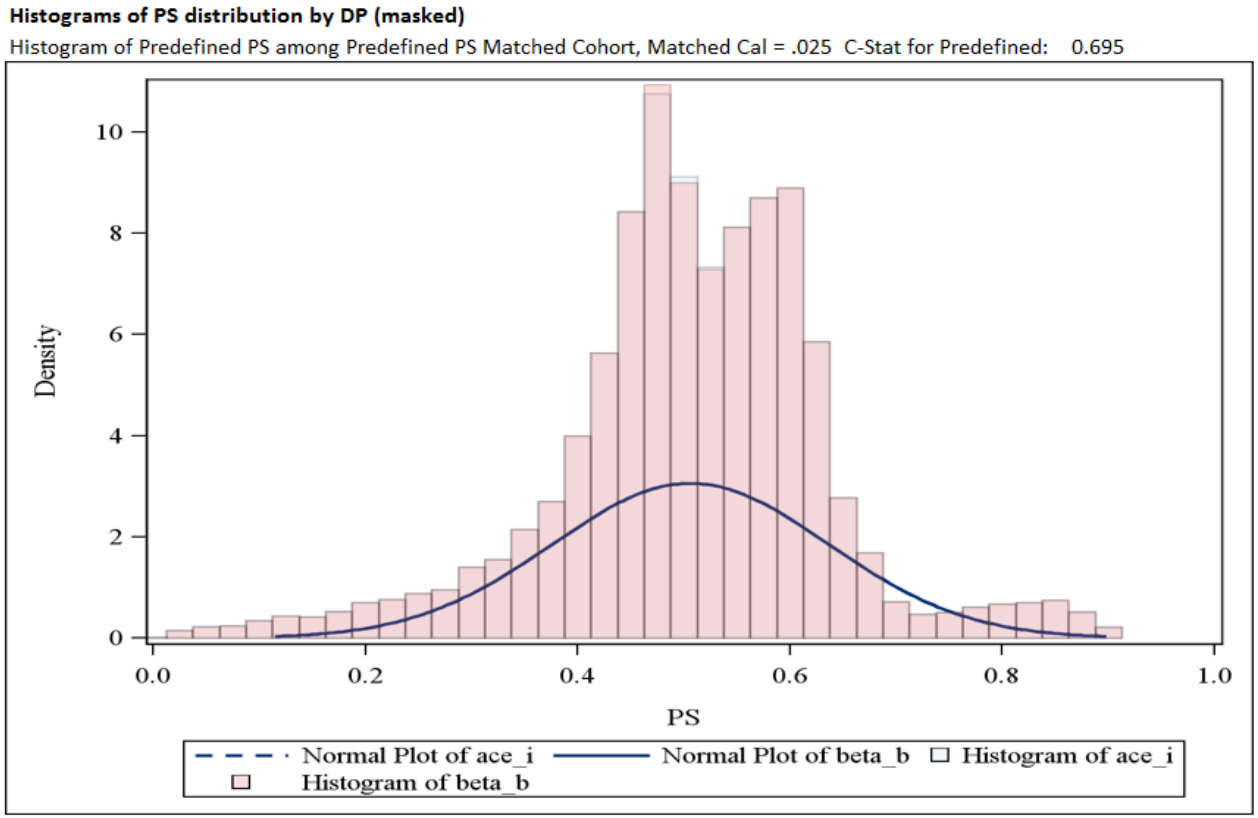
Propensity Scores After Match



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Angioedema: Table 3. Results

Table 3: Sequential Estimates for Angioedema Events by Analysis Type, and Drug Pair

Exposure Definition	Monitoring Period	New Users	Person Years at Risk	Average Person Years at Risk	Number of Events
Unmatched Analysis (Site-adjusted only)					
ACE Inhibitors	1	2,211,215	1,131,526	0.51	5,158
Beta Blockers		1,673,682	683,614	0.41	1,292
1:1 Matched Analysis; Caliper=0.025					
ACE Inhibitors	1	1,309,104	658,700	0.50	3,311
Beta Blockers		1,309,104	544,285	0.42	988

Incidence Rate per 1000 Person Years	Risk per 1000 New Users	Difference per 1000 Person Years	Difference in Risk per 1000 New Users	Hazard Ratio (95% CI)	Wald P-Value
4.558	2.33	2.67	1.56	2.55 (2.40, 2.71)	<.0001
1.890	0.77				
5.027	2.53	3.21	1.77	3.14 (2.86, 3.44)	<.0001
1.815	0.75				

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Angioedema: Table 3. Results

ACEI vs β-blocker 1:1 matched analysis:

- **HR = 3.1**
  (95% CI, 2.9-3.4)

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Example Request Assessment
Trial to Assess Chelation Therapy (TACT) Replication

- Plan to replicate the TACT trial – EDTA chelation to prevent coronary heart disease – focusing on diabetic patients
- **Inclusion criteria**
  - > 50 years old
  - Confirmed diagnosis of diabetes on medical therapy (insulin or oral)
  - Previous myocardial infarction

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EASY: All inclusion criteria are available for querying using existing cohort identification programs

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  - IMPOSSIBLE: Smoking status not recorded in claims and unreliable in EHRs

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  - EASY: Available
- No chelation therapy in prior 5 years
  - Probably EASY: Need to assess data capture reliability and payment policies

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- Question: What are the demographic characteristics of patients that might be eligible – race, gender, age? What about comorbidities?

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Example Request Assessment
Trial to Assess Chelation Therapy (TACT) Replication

- Question: What are the demographic characteristics of patients that might be eligible – race, gender, age? What about comorbidities?
  - EASY: Age, sex, and comorbidities can be defined and presented
  - IMPOSSIBLE: Race is recorded for a subset of patients

Example Request Assessment
Trial to Assess Chelation Therapy (TACT) Replication

- Question: What can you tell us about where patients who meet these criteria receive most of their care – primary care offices, cardiology offices, endocrinology clinics? Does this vary in urban, suburban, more rural communities?

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Example Request Assessment
Trial to Assess Chelation Therapy (TACT) Replication

- What can you tell us about the uncertainties in these estimates?

Example Request Assessment
Trial to Assess Chelation Therapy (TACT) Replication

- What can you tell us about the uncertainties in these estimates?
  - Suggest using sensitivity analyses to assess importance of each definition

Example Request Assessment

Follow Up of Abnormal Cancer Screening Tests

Request: Characterize rate of follow-up of abnormal cancer screening tests, including mammography, fecal immunochemical (FIT), or Pap tests within a managed care population

Example Request Assessment
Follow Up of Abnormal Cancer Screening Tests

- Identification of benefit design – to define “managed care” – is possible but complex

Example Request Assessment
Follow Up of Abnormal Cancer Screening Tests

- Identification of benefit design – to define “managed care” – is possible but complex
  - Assessment of complexity and validity over time is needed
  - Definition of “managed care”

Example Request Assessment

Follow Up of Abnormal Cancer Screening Tests

1. How many are screened for each cancer?
2. How many have abnormal screening test results?
3. How many abnormal results appear to have no further testing?
   a. For mammography – no additional mammography, ultrasound, MRI or biopsy with 90 days
   b. For FIT – no colonoscopy within 90 days
   c. For PAP – no repeat PAP that is normal, or no colposcopy within 90 days
4. Is there other evidence of evaluation of the abnormality?

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4. Is there other evidence of evaluation of the abnormality?

EASY: Questions 1-4 can be answered using existing data and programs

Example Request Assessment

Follow Up of Abnormal Cancer Screening Tests

5. Does the rate of follow up of abnormal test results vary across practices?

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What are the race and age breakdowns of patients?

Example Request Assessment

Follow Up of Abnormal Cancer Screening Tests

5. Does the rate of follow up of abnormal test results vary across practices?

   HARD: Facility and provider codes are available; new programming and discussion with data partners would be required

What are the race and age breakdowns of patients?

- EASY: Age distribution

Example Request Assessment

Follow Up of Abnormal Cancer Screening Tests

5. Does the rate of follow up of abnormal test results vary across practices?

HARD: Facility and provider codes are available; new programming and discussion with data partners would be required

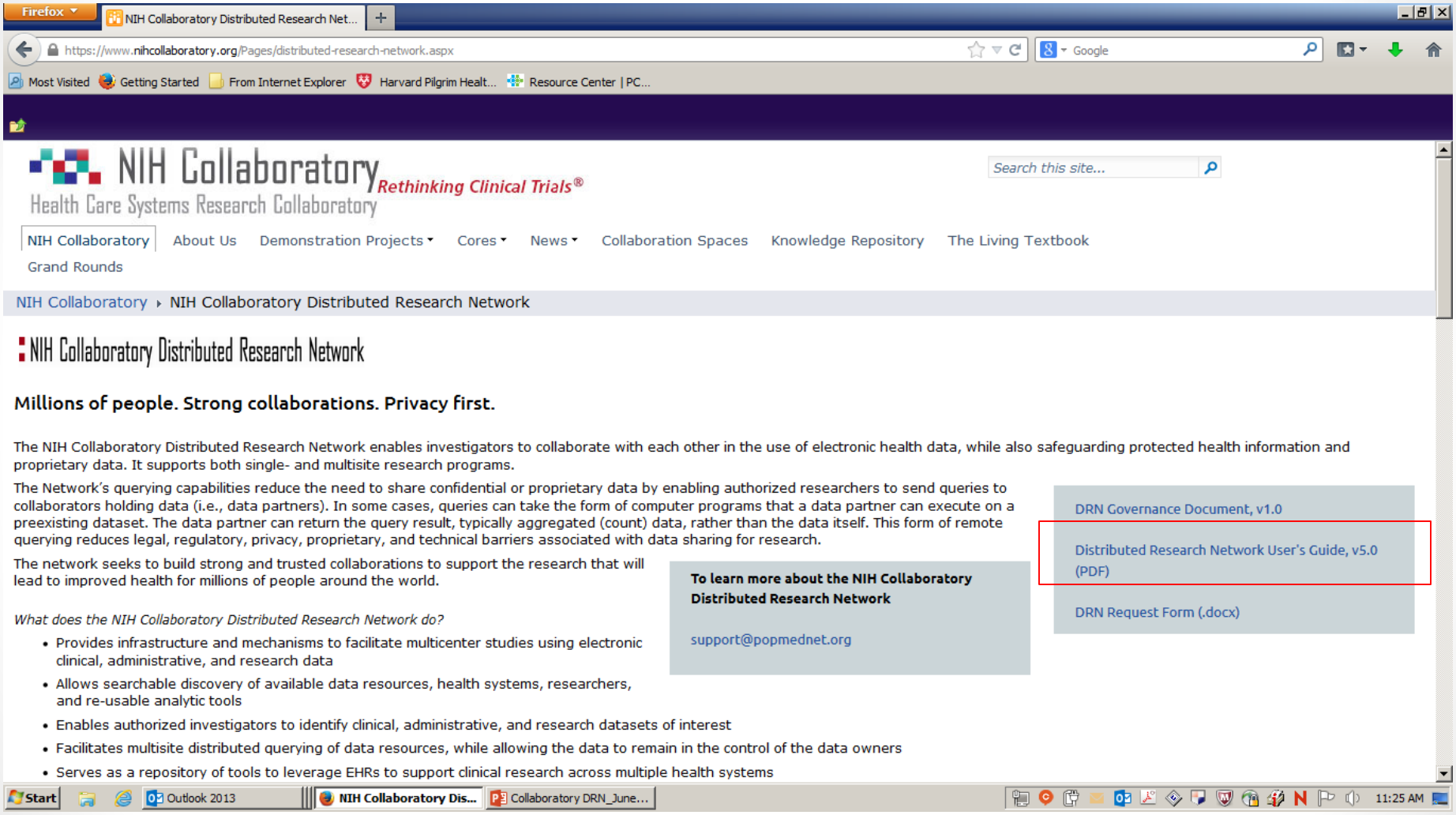
What are the race and age breakdowns of patients?

- EASY: Age distribution
- IMPOSSIBLE: Race

How to Use the NIH Collaboratory Distributed Research Network

- Data Partners participate on a project-by-project-basis
- Submit requests using the NIH Collaboratory DRN request form
- The DRN Coordinating Center reviews each request to assess appropriateness and level of effort
- Costs: on a case-by-case basis

https://www.nihcollaboratory.org/Pages/distributed-research-network.aspx



Thank you!