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Comparing Registry and Electronic Health Record (EHR) Data for Real-World Evidence Generation

Heart Failure as a Case Study

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Introductions

Nam Nguyen

VP, MEDICAL INFORMATICS AND DATA SCIENCE

Nam is a health data addict spending the last 15 years transforming health data into insights at MedVantage, IMS Health, Practice Fusion, and Veradigm.

Mac Bonafede

VP, REAL WORLD EVIDENCE

Mac is a recovering academic who joined Veradigm from IBM Watson Health. He adjuncts in Health Data Science at the University of New Hampshire and fixes up his old farmhouse for fun.

Special thanks to Jordan Overcash and Kevin Lavelle for conducting the underlying analyses presented here.

Overview

Background

Generating real-world evidence (RWE) of patients with heart failure requires clinical data elements not commonly found in administrative databases, specifically left ventricular ejection fraction (LVEF) and body mass index (BMI).

Objective

To compare and contrast the view of patients with heart failure from the perspective of the PINNACLE® Registry, a large cardiovascular disease registry developed by the American College of Cardiology, with those identified in the Practice Fusion ambulatory electronic health record (EHR) database.

RESULTS

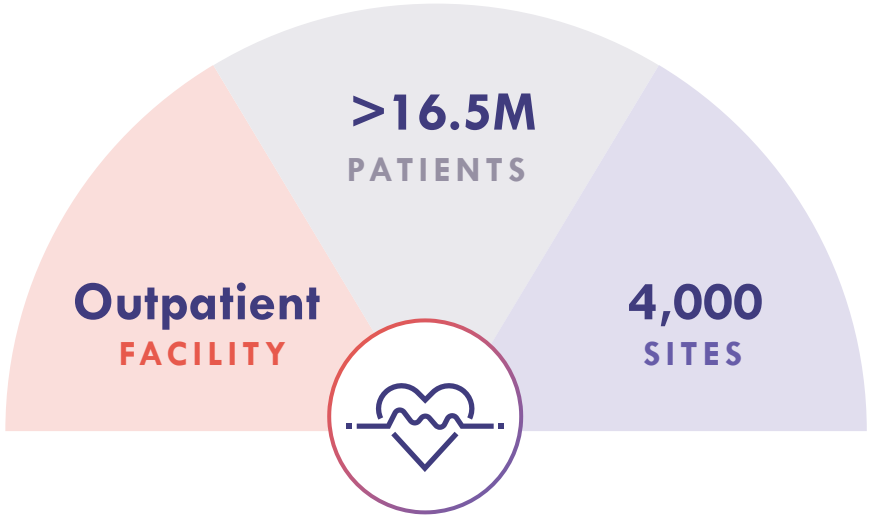
Both data sources represent large collections of real-world data (RWD) across the United States, but from different perspectives.

- PINNACLE primarily represents cardiologists and related specialists.
- Practice Fusion contains primary care physicians and specialists in ambulatory, community-based healthcare practices.

Differences between these types of data sources have deep implications for identifying key patient populations within RWD sources in terms of both understanding heart failure management, as well as potential recruitment for observational research or clinical trials.

Methods

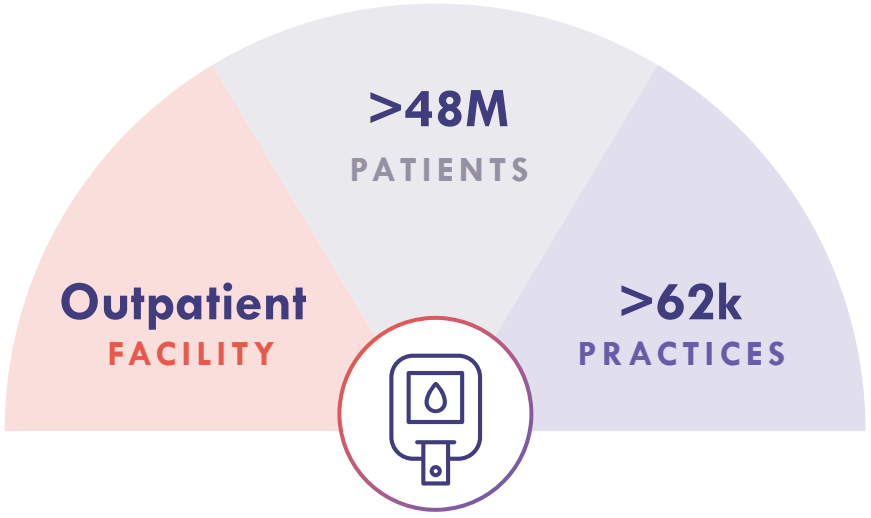
Data Sources | By the Numbers (2015 – 2020)



PINNACLE Registry

Coronary artery disease, heart failure, atrial fibrillation, hypertension, diabetes, peripheral arterial disease

The PINNACLE Registry is a Veradigm Network Solution

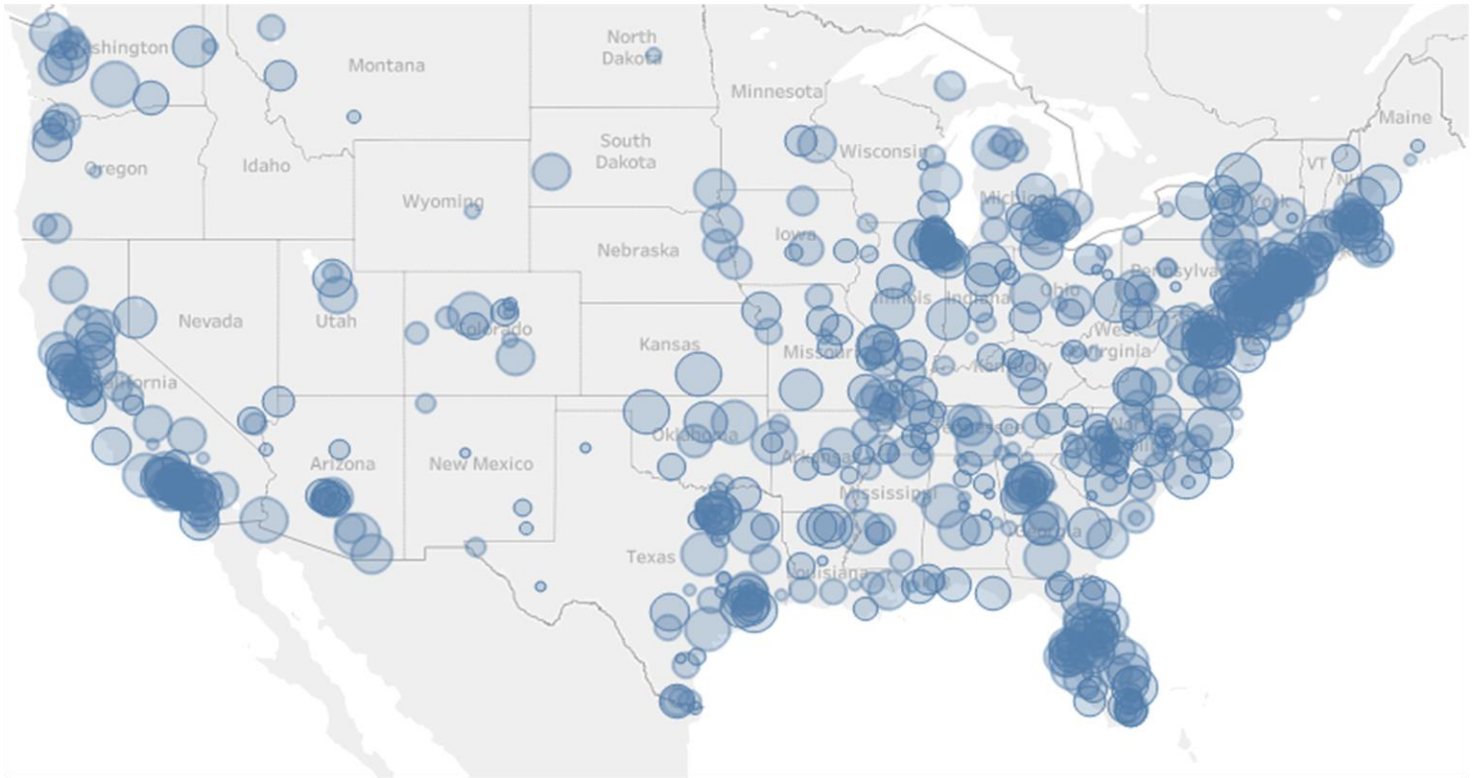


Practice Fusion

Primary care and ambulatory care specialties

Practice Fusion is a Veradigm Network Solution

PINNACLE Registry | Footprint



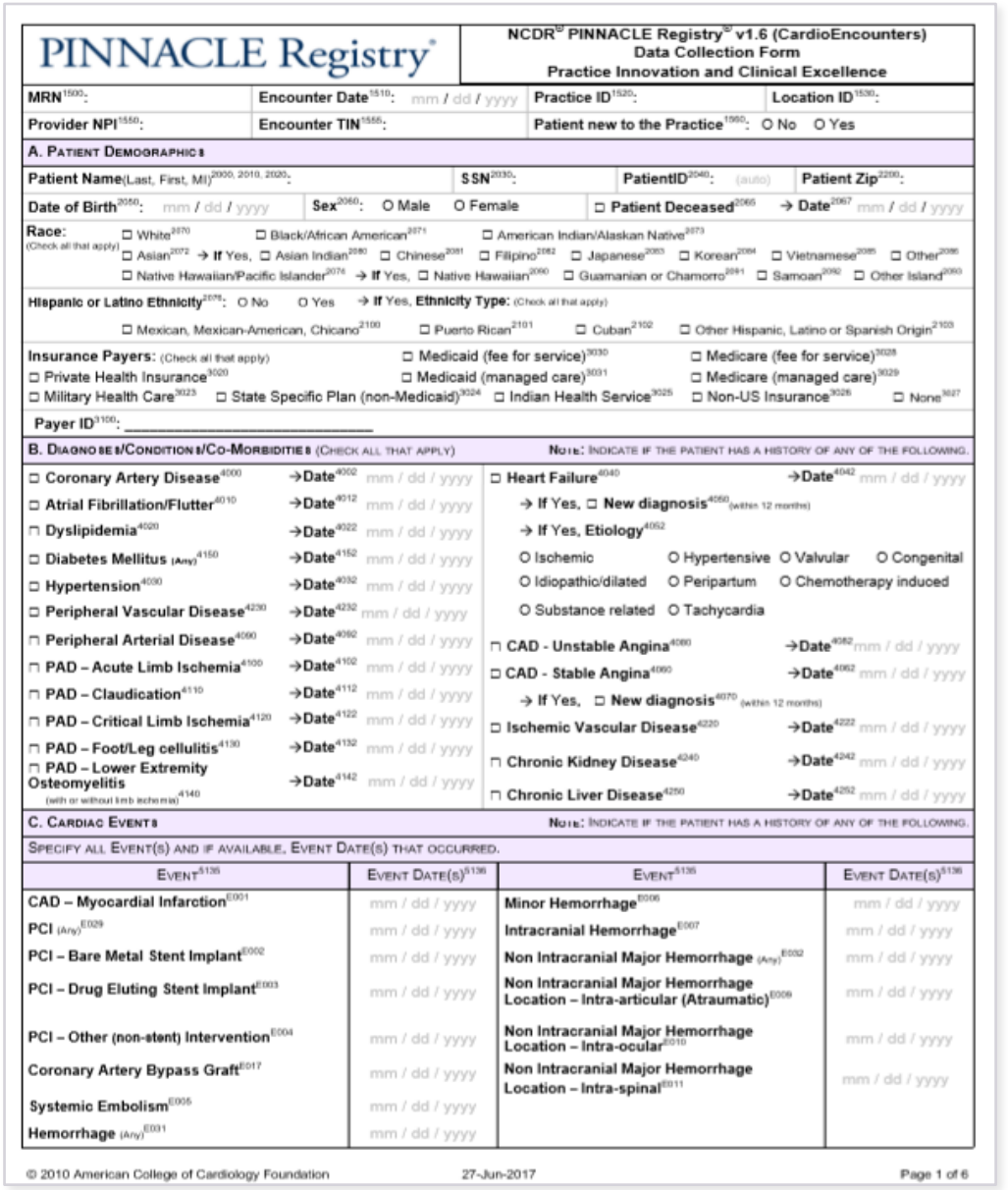
- Founded in **2008**
- Largest US outpatient CV registry
- **88.8M** records
- **16.5M** unique patient lives
- **13K** providers
- **4K** office locations
- CAD, HF, AF, HTN, PAD, PC
- **24** Measures

Data as of February 2022

veradigm NETWORK | The PINNACLE Registry is a Veradigm Network Solution

Data pulled and mapped directly from each site's EHR

- Patient Demographics
- Activity Assessment
- Diagnosis/Conditions (LVEF, HF, CAD)
- Cardiac events and comorbidities
- Exams and procedures (foot, eye, renal, cardiac, hypertension)
- Lab values
- Other medications (antianginal, antiarrhythmic, anticoagulants, antihypertensive, beta blockers)



PINNACLE Registry®

NCDR® PINNACLE Registry® v1.6 (CardioEncounters)
Data Collection Form
Practice Innovation and Clinical Excellence

MRN[1500]: | Encounter Date[1510]: mm / dd / yyyy | Practice ID[1520]: | Location ID[1530]:

Provider NPI[1550]: | Encounter TIN[1555]: | Patient new to the Practice[1560]: O No O Yes

A. Patient Demographics

Patient Name(Last, First, MI)[2000, 2010, 2020]: | SSN[2030]: | PatientID[2040]: (auto) | Patient Zip[2200]:

Date of Birth[2050]: mm / dd / yyyy | Sex[2060]: O Male O Female | ☐ Patient Deceased[2065] → Date[2067] mm / dd / yyyy

Race: (Check all that apply) ☐ White[2070] ☐ Black/African American[2071] ☐ American Indian/Alaskan Native[2073] ☐ Asian[2072] → If Yes, ☐ Asian Indian[2080] ☐ Chinese[2081] ☐ Filipino[2082] ☐ Japanese[2083] ☐ Korean[2084] ☐ Vietnamese[2085] ☐ Other[2086] ☐ Native Hawaiian/Pacific Islander[2076] → If Yes, ☐ Native Hawaiian[2090] ☐ Guamanian or Chamorro[2091] ☐ Samoan[2092] ☐ Other Island[2093]

Hispanic or Latino Ethnicity[2078]: O No O Yes → If Yes, Ethnicity Type: (Check all that apply) ☐ Mexican, Mexican-American, Chicano[2100] ☐ Puerto Rican[2101] ☐ Cuban[2102] ☐ Other Hispanic, Latino or Spanish Origin[2103]

Insurance Payers: (Check all that apply) ☐ Private Health Insurance[3020] ☐ Medicaid (fee for service)[3030] ☐ Medicaid (managed care)[3031] ☐ Medicare (fee for service)[3028] ☐ Medicare (managed care)[3029] ☐ Military Health Care[3023] ☐ State Specific Plan (non-Medicaid)[3024] ☐ Indian Health Service[3025] ☐ Non-US Insurance[3026] ☐ None[3027]

Payer ID[3100]: _____

B. Diagnoses/Conditions/Co-Morbidities (Check all that apply) Note: Indicate if the patient has a history of any of the following.

☐ Coronary Artery Disease[4000]	→Date[4002] mm / dd / yyyy	☐ Heart Failure[4040]	→Date[4042] mm / dd / yyyy
☐ Atrial Fibrillation/Flutter[4010]	→Date[4012] mm / dd / yyyy	→ If Yes, ☐ New diagnosis[4060] (within 12 months)	
☐ Dyslipidemia[4020]	→Date[4022] mm / dd / yyyy	→ If Yes, Etiology[4062]	
☐ Diabetes Mellitus (Any)[4150]	→Date[4152] mm / dd / yyyy	O Ischemic O Hypertensive O Valvular O Congenital	
☐ Hypertension[4030]	→Date[4032] mm / dd / yyyy	O Idiopathic/dilated O Peripartum O Chemotherapy induced	
☐ Peripheral Vascular Disease[4230]	→Date[4232] mm / dd / yyyy	O Substance related O Tachycardia	
☐ Peripheral Arterial Disease[4090]	→Date[4092] mm / dd / yyyy	☐ CAD - Unstable Angina[4080]	→Date[4082] mm / dd / yyyy
☐ PAD – Acute Limb Ischemia[4100]	→Date[4102] mm / dd / yyyy	☐ CAD - Stable Angina[4090]	→Date[4062] mm / dd / yyyy
☐ PAD – Claudication[4110]	→Date[4112] mm / dd / yyyy	→ If Yes, ☐ New diagnosis[4070] (within 12 months)	
☐ PAD – Critical Limb Ischemia[4120]	→Date[4122] mm / dd / yyyy	☐ Ischemic Vascular Disease[4220]	→Date[4222] mm / dd / yyyy
☐ PAD – Foot/Leg cellulitis[4130]	→Date[4132] mm / dd / yyyy	☐ Chronic Kidney Disease[4240]	→Date[4242] mm / dd / yyyy
☐ PAD – Lower Extremity Osteomyelitis (with or without limb ischemia)[4140]	→Date[4142] mm / dd / yyyy	☐ Chronic Liver Disease[4250]	→Date[4252] mm / dd / yyyy

C. Cardiac Events Note: Indicate if the patient has a history of any of the following.

Specify all Event(s) and if available, Event Date(s) that occurred.

Event[5135]	Event Date(s)[5136]	Event[5135]	Event Date(s)[5136]
CAD – Myocardial Infarction[E001]	mm / dd / yyyy	Minor Hemorrhage[E006]	mm / dd / yyyy
PCI (Any)[E029]	mm / dd / yyyy	Intracranial Hemorrhage[E007]	mm / dd / yyyy
PCI – Bare Metal Stent Implant[E002]	mm / dd / yyyy	Non Intracranial Major Hemorrhage (Any)[E032]	mm / dd / yyyy
PCI – Drug Eluting Stent Implant[E003]	mm / dd / yyyy	Non Intracranial Major Hemorrhage Location – Intra-articular (Atraumatic)[E009]	mm / dd / yyyy
PCI – Other (non-stent) Intervention[E004]	mm / dd / yyyy	Non Intracranial Major Hemorrhage Location – Intra-ocular[E010]	mm / dd / yyyy
Coronary Artery Bypass Graft[E017]	mm / dd / yyyy	Non Intracranial Major Hemorrhage Location – Intra-spinal[E011]	mm / dd / yyyy
Systemic Embolism[E005]	mm / dd / yyyy		
Hemorrhage (Any)[E031]	mm / dd / yyyy		

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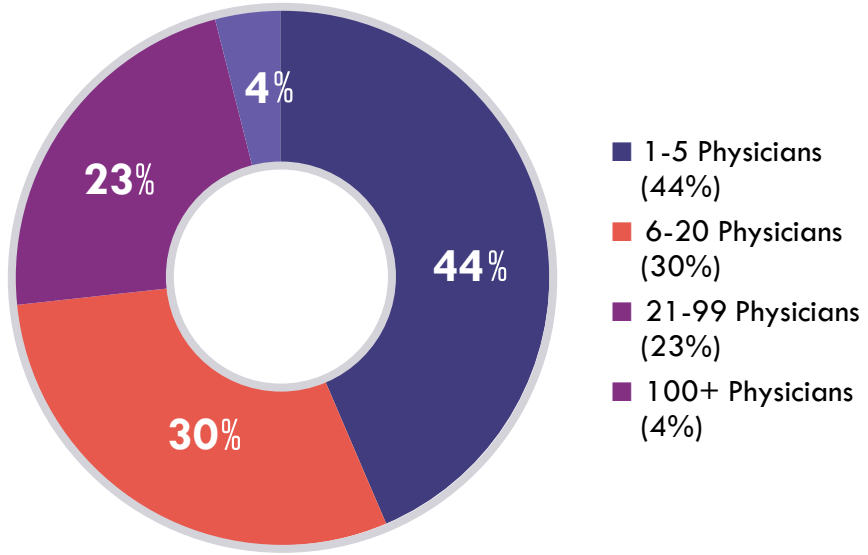
Who is the PINNACLE Registry User?

TOP SPECIALTIES

- Cardiology
- Family Medicine
- Internal Medicine



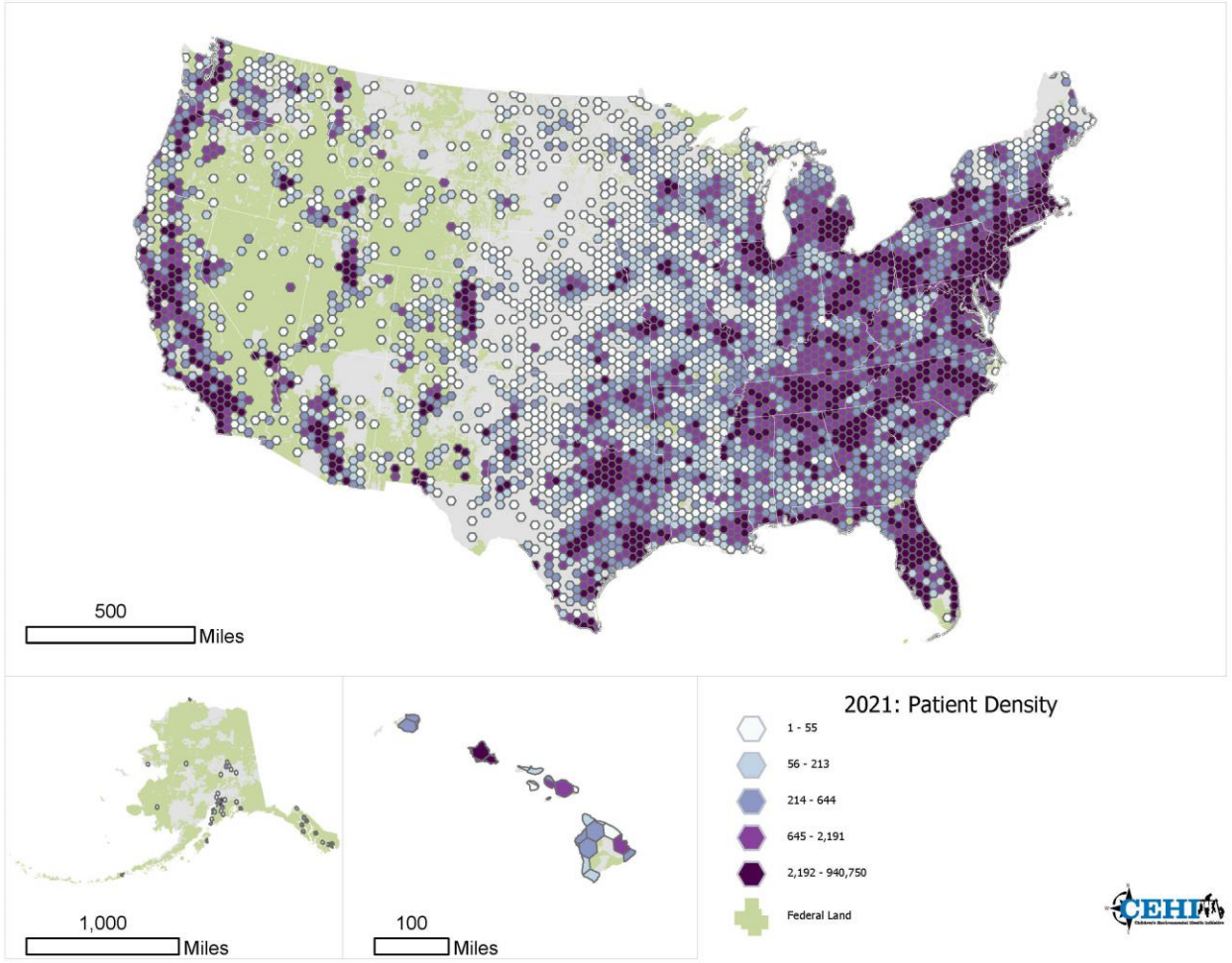
88.8 MILLION
PATIENT RECORDS

4,000
SITES

Practice Fusion | Footprint

- **Cloud-based EHR that includes both primary care providers and specialists in all 50 states.**

- **In the last 5 years, Practice Fusion includes over 48 million patients corresponding to >123k providers in >62k practices.**



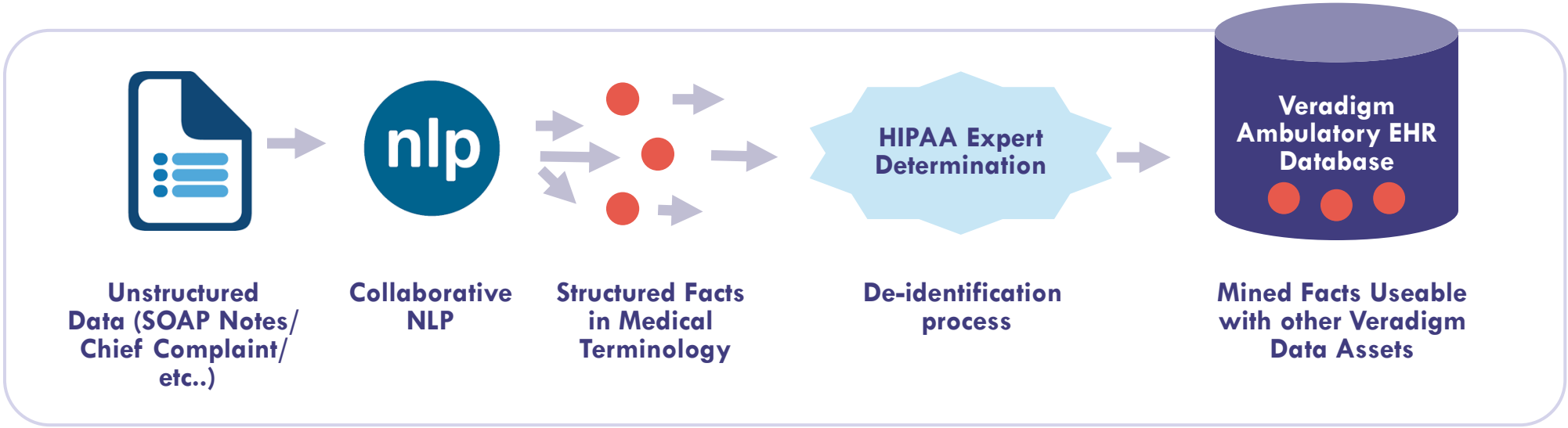
veradigm NETWORK | Practice Fusion is a Veradigm Network Solution

Practice Fusion Database Overview

Research databases grouped into categories (e.g., visits, diagnoses, prescriptions, and labs)

CATEGORY	MAJOR ELEMENTS
Patient	Patient demographics (such as year of birth, gender, geography, race, ethnicity)
Provider	Specialty, geography, practice link
Visit	Visits, vitals (BMI, BP, Pulse), encounter events, problem list
Medical History	Immunizations, allergies, and smoking status
Diagnosis	ICD9, ICD10, SNOMED, created date, active flag
Prescription	NDC, Rx/written/documented, quantity, refills, pharmacy
Lab	LOINC number, quantitative result, lab vendor
Insurance	Payer details, plan details, payment type
Lookup	Last data refresh date

Note and Free-Text Access Based on Mining and then De-identifying Clinical Facts



- **Access to notes** and other free text data in a collaborative approach of data scientists and clinical experts
- **Resultant data de-identified and translated** into appropriate medical terminology (ICD, SNOMED, LOINC, etc.) to incorporate back into Veradigm data assets

LVEF Example | Mining Unstructured Clinical Events

LVEF is needed for a Heart Failure study, however very few structured LVEF values exist in the RWD source.

- Providers **are** documenting LVEF scores in their unstructured clinical notes or semi-structured free text fields instead of in structured fields.
  - *How can we increase our patient data subset for LVEF patients?*

Data Enrichment Services used NLP to structure and de-identify LVEF events and associated scores from ambulatory SOAP notes and semi-structured free text values.

BEFORE: LVEF events with scores in structured LOINC with quantitative value = 4865

AFTER DATA ENRICHMENT: LVEF events with scores

- From SOAP Notes: >3.7M
- From Semi-structured free text value: >3.6M

Results

Patient Selection

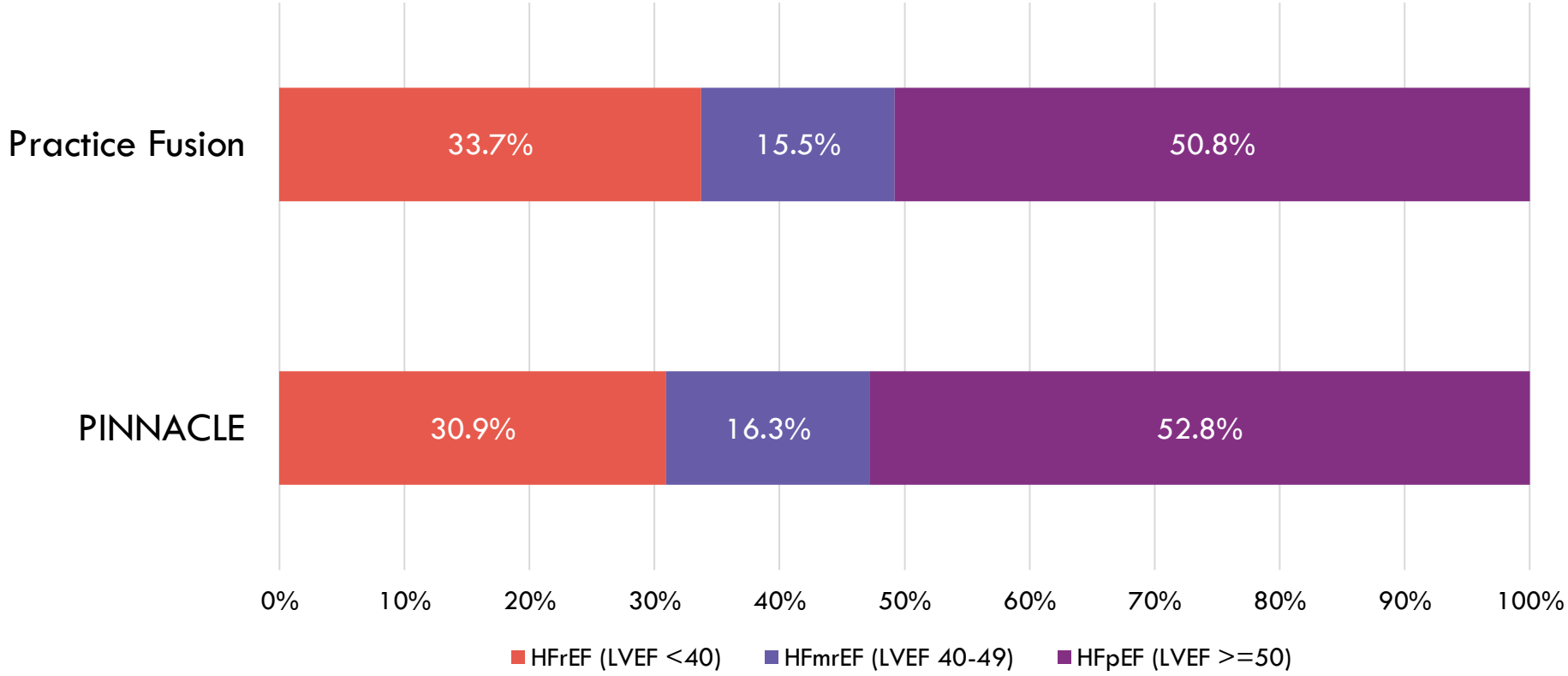
	PINNACLE		PRACTICE FUSION	
	N	%	N	%
Patients with heart failure				
Patients with ≥1 diagnosis for heart failure: 2015-2020	812,431	100%	645,243	100%
With a Left Ventricular Ejection Fraction between 01/01/2016 and12/31/2019 (Index date = first LVEF date)	335,593	41.3%	36,209	5.6%
Body mass index (BMI) measurement within 365 days of index date[1]	283,119	34.8%	31,749	4.9%
LVEF Strata				
Patients with index LVEF >= 50	149,439	52.8%	16,123	50.8%
Patients with index LVEF 40-49	46,061	16.3%	4,922	15.5%
Patients with index LVEF < 40	87,619	30.9%	10,704	33.7%

Demographics

	PINNACLE		PRACTICE FUSION	
	N	%	N	%
Age, Index Date (Mean, SD)	67.76	9.99	70.11	12.24
Age Group, Index Date (N,%)				
18-44	10,482	3.7%	1,152	3.6%
45-54	21,538	7.6%	2,559	8.1%
55-64	49,699	17.6%	5,739	18.1%
65-74	112,800	39.8%	8,861	27.9%
75-79	88,600	31.3%	4,526	14.3%
80+	-	0.0%	8,912	28.1%
BMI, Closest to Index Date	32.01	8.22	30.50	7.59
<18	2,270	0.8%	322	1.0%
18-24	52,013	18.4%	6,403	20.2%
25-30	79,256	28.0%	11,176	35.2%
>30	149,580	52.8%	13,848	43.6%
Female (N, %)	126,024	44.5%	14,414	45.4%
Race/Ethnicity (N,%)				
Non-Hispanic White	152,138	53.7%	10,023	31.6%
Non-Hispanic Black	27,406	9.7%	2,933	9.2%
Hispanic	12,807	4.5%	4,473	14.1%
Other/Unknown	90,768	32.1%	14,320	45.1%

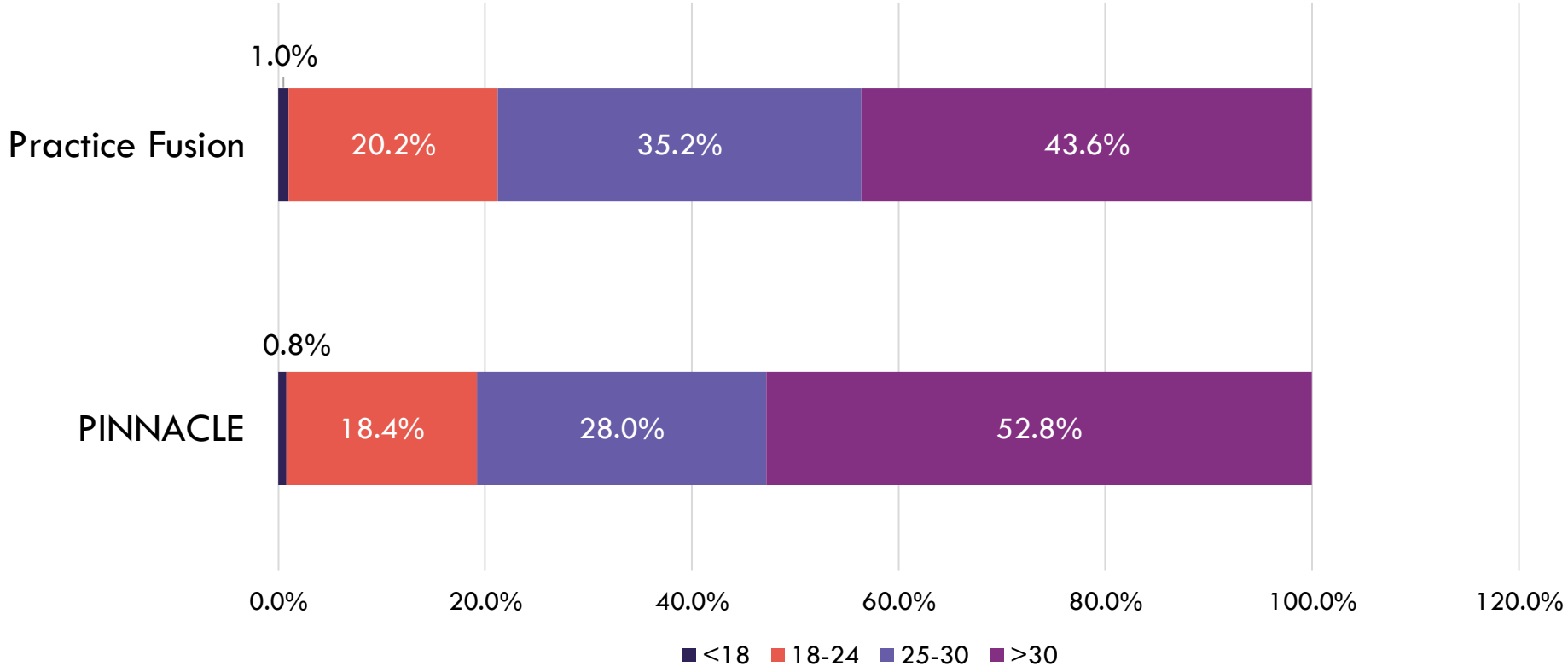
LVEF

LVEF was similar between data sources, with approximately one-third with HFrEF and one-half with HFpEF



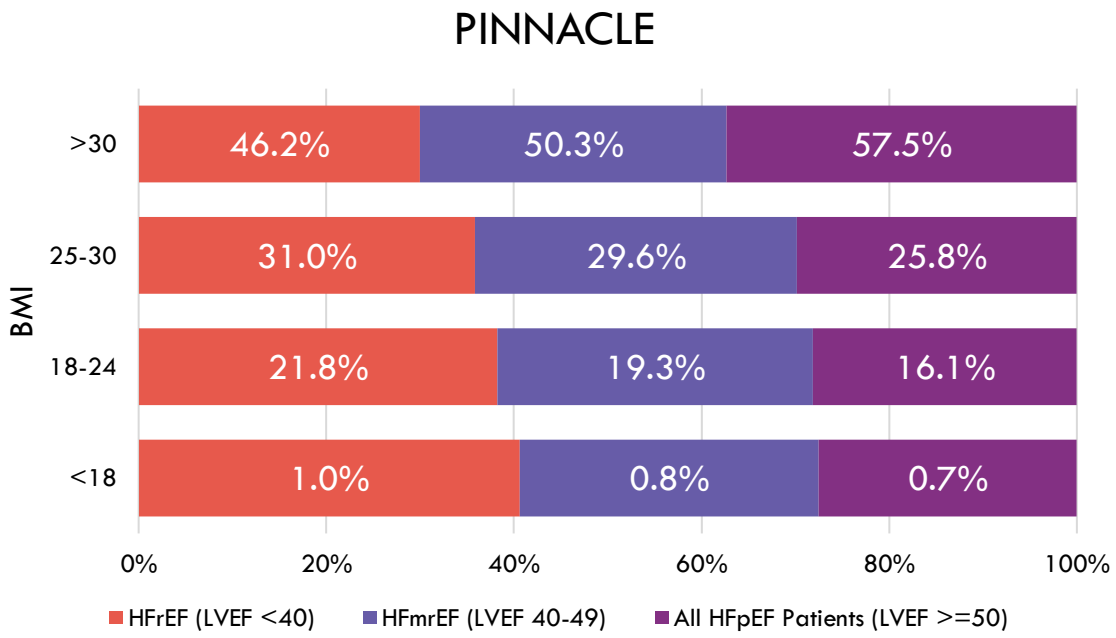
BMI

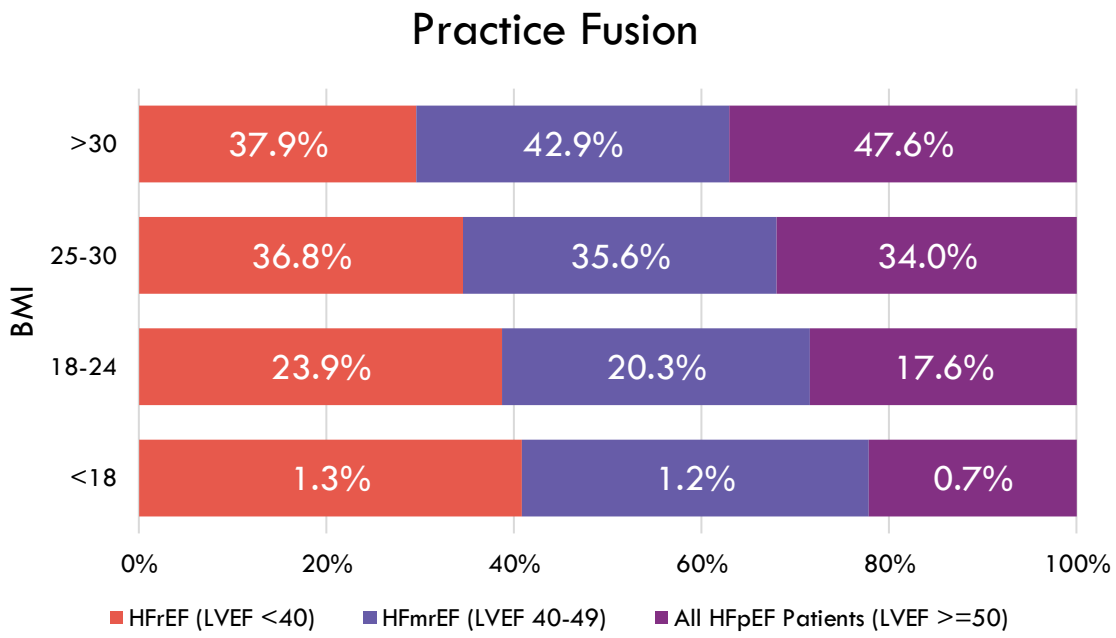
BMI was similar between data sources, with approximately four-out-of-five patients overweight or obese



LVEF x BMI

The distribution of LVEF by BMI differed slightly between data sources, with patients with BMI>30 in PINNACLE being slightly more likely to have HFrEF while patients with BMI 25-30 in Practice Fusion were more likely to have HFrEF





Cardiovascular Clinical Characteristics

	PINNACLE	PRACTICE FUSION
Comorbidities (N,%)	94.5%	90.5%
Atrial Fibrillation	41.4%	28.4%
Coronary Artery Disease	58.3%	35.3%
Coronary Artery Bypass Surgery	11.2%	2.4%
Chronic Kidney Disease	14.3%	21.5%
Diabetes	32.1%	36.7%
Hypertension	78.9%	76.2%
Myocardial Infarction	13.0%	10.3%
Peripheral Artery Disease	14.4%	16.2%
Prior Stroke /TIA	13.5%	10.0%
Heart Failure Medications (N,%)	97.0%	44.2%
ACE inhibitors	49.1%	11.7%
Angiotensin II Receptor Blockers	34.0%	14.3%
Angiotensin-Receptor Neprilysin Inhibitors (Sacubitril/valsartan)	8.9%	2.5%
Beta Blockers	87.8%	27.5%
If Channel Blockers (Ivabradine)	0.6%	0.2%
Diuretics	77.3%	26.7%
SGLT2 Inhibitors	2.8%	0.7%
2 or more of the following class of medications: ACE inhibitors, ARBs, Renin Inhibitors	9.4%	1.5%

Clinical Characteristics

	PINNACLE	PRACTICE FUSION
Concomitant Medications (N,%)	94.4%	39.3%
Antianginal	23.6%	0.8%
Antiarrhythmic	29.3%	3.2%
Anticoagulants	40.5%	9.6%
Antidiabetic2	28.4%	8.4%
○ Insulin	13.7%	3.3%
○ Metformin	21.1%	5.6%
○ Pioglitazone	2.3%	0.5%
○ Rosiglitazone	0.2%	0.0%
○ DPP-4 Inhibitors	5.5%	1.7%
○ Alpha-glucosidase Inhibitors	0.2%	0.0%
Antiplatelet	0.2%	8.3%
Calcium Channel Blockers	37.7%	0.0%
Lipid Lowering Drugs	75.5%	22.9%
Thrombin Receptor Antagonist	2.7%	0.0%

Discussion

Implications for Prospective Research and Data Collection

Both data sources can facilitate prospective projects

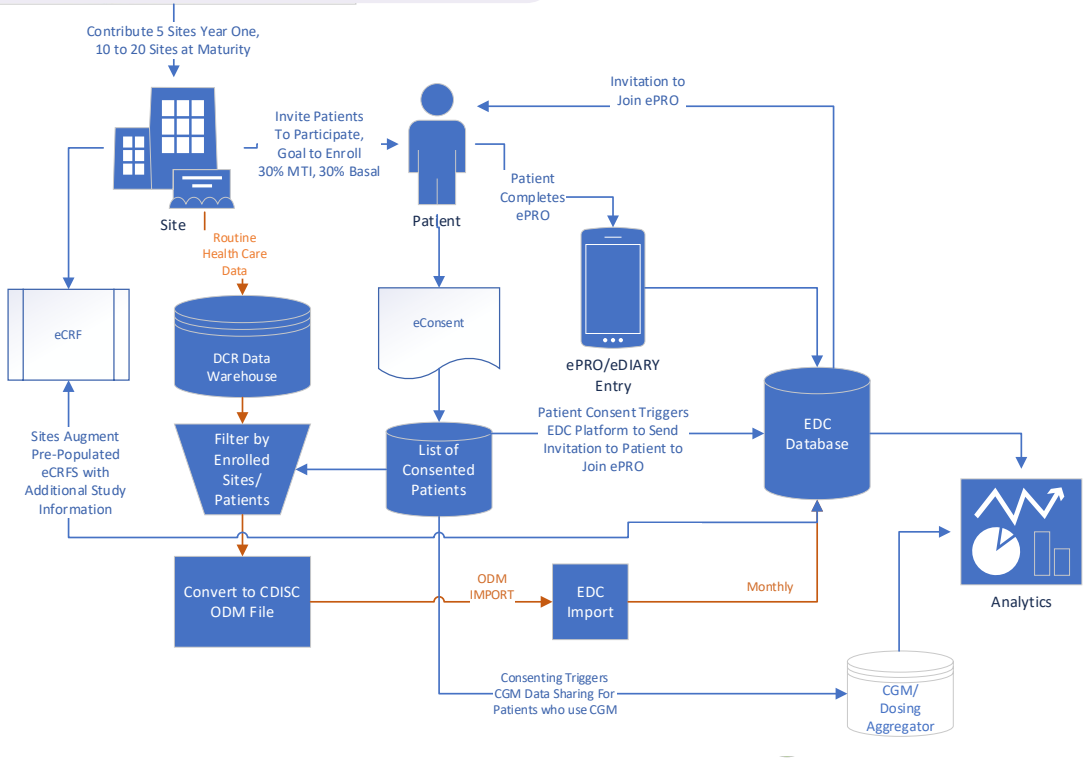
Provider support and buy-in is critical

- Early projects have focused on drug safety and post-marketing surveillance.

While the mechanisms and data flow differ by data source, each has distinct strengths

Both data sources can offer patients access to research opportunities, bringing research to the point of care

Customized study portal, prioritized to sites with preferred sample characteristics



Summary

Both the PINNACLE Cardiovascular Registry and Practice Fusion EHR can offer real-world insights into patients with heart failure, incorporating a range of clinical measures often missing from administrative databases.

Both data sources exist as structured, retrospective real-world databases but can also be used for prospective observational research.

WHERE THE DATA SOURCES DIFFER IS IN:

The means of engaging patients in research activities and the composition of the participating sites.

Research approach needs to incorporate these differences in the study design and planned implications.

Accessibility of necessary clinical information.

LVEF is a structured field in PINNACLE but can only be accessed through mining unstructured and semi-structured fields in Practice Fusion.

Further efforts are needed to unlock the insights contained in unstructured and semi-structured fields.

Thank You.
Any Questions?

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