Leveraging *Informatics in Pragmatic Research: Initial Experience in PCORnet*

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Disclosures

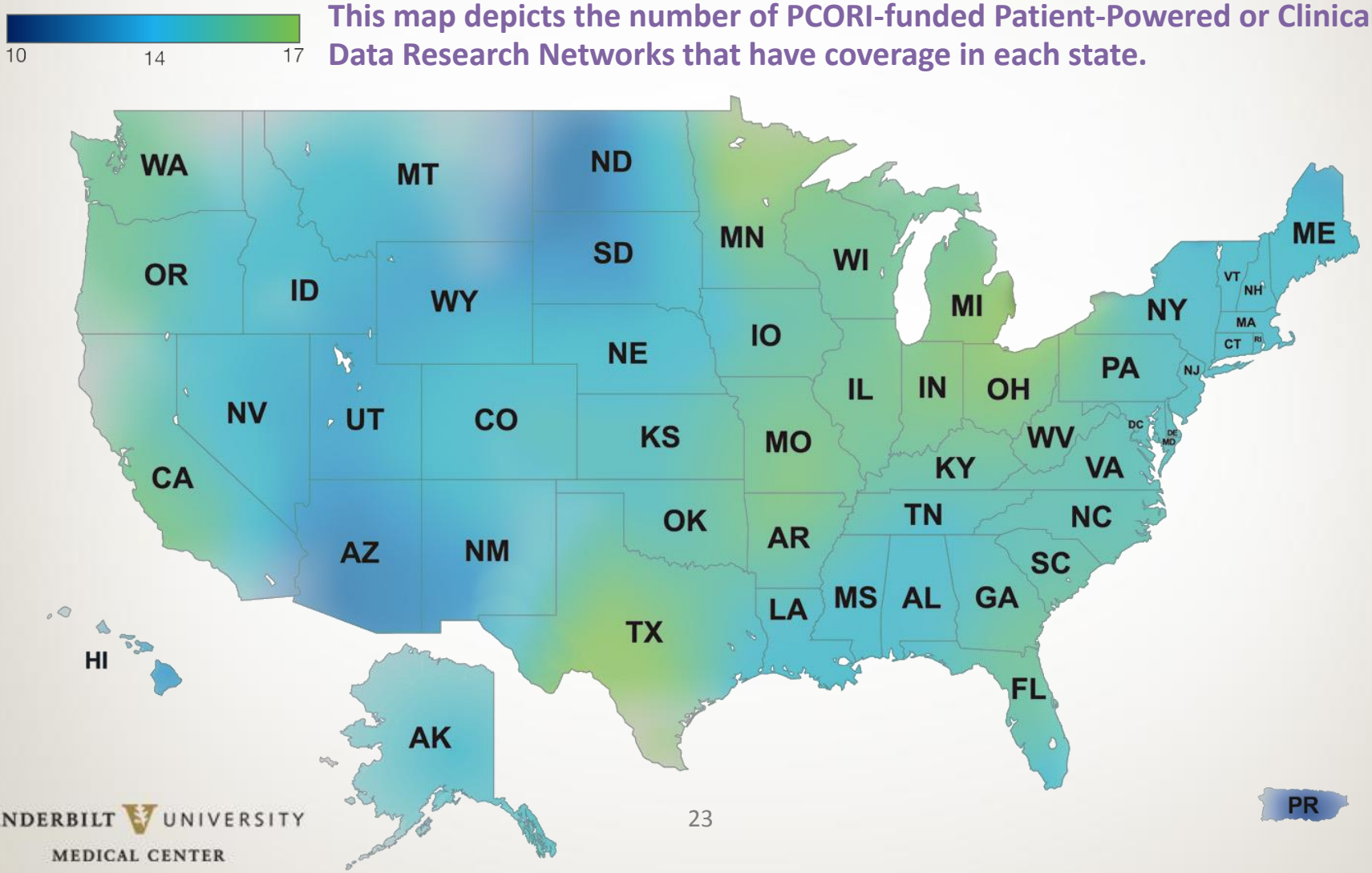
- **Current Funding Support:** NICHD (R01), NCATS (VICTR), NIDDK (P30), PCORI, CMS

- **Disclosures:** EdLogics (Advisory Board), Boehringer Ingelheim

PCORI Initiative: PCORnet

- Patient Centered Outcomes Research Institute (PCORI) created PCORnet with:
  - 13 sites as Clinical Data Research Networks (CDRN)
  - 20 sites as Patient Powered Research Networks (PPRN)
- Goals
  - Each CDRN engages 1 million or more patients across 2 or more health systems
  - Build infrastructure to share data, build novel informatics tools, engage key stakeholders
  - Perform comparative effectiveness research and pragmatic clinical trials.

PCORnet Reaches Across the Nation



Pragmatic Research: Use Cases

1. De-identified data/HIPAA Limited data for prep to research or observational research
2. Fully-identified data for observational research
3. Contact patients for observational (survey or cohort) research
4. Pragmatic intervention studies at patient, clinic, or system level to answer practical clinical questions and improve patient care
5. Health system innovation and population health efforts

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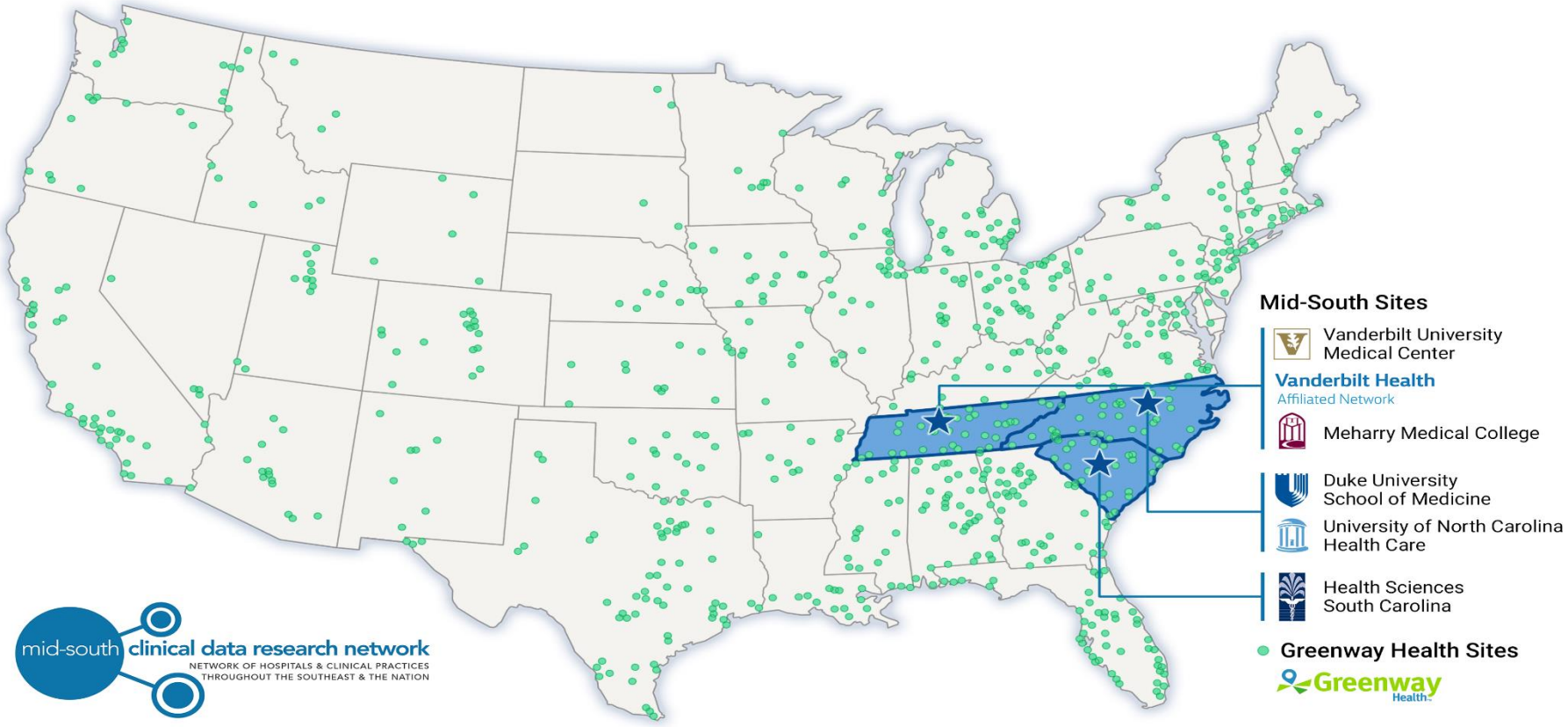
Les Lenert MD, Health Sciences of South Carolina

Mid-South CDRN Clinical Reach

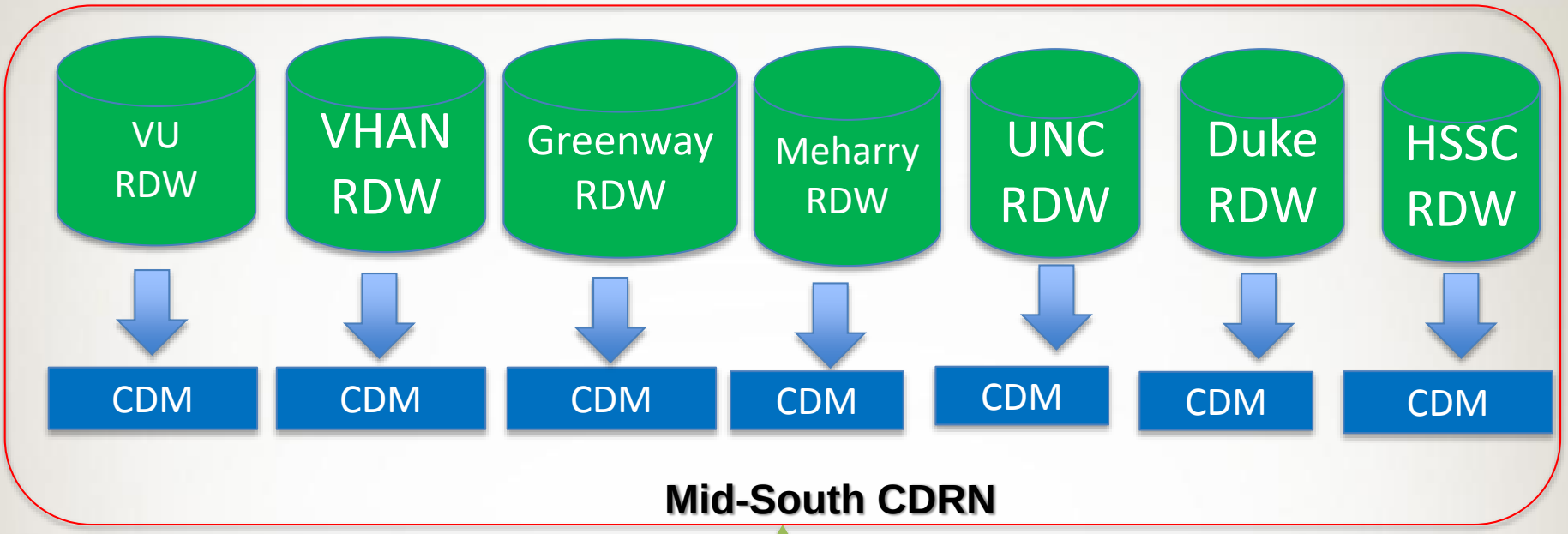
Over **9 million patients** in the **Mid-South Region.**

The Mid-South Clinical Data Research Network includes **clinical records** of patients **since 2004** and is updated on a quarterly basis.

Our partnership with **Greenway Health** adds over **16 million** patients nationwide.



Data Aggregation Across CDRN

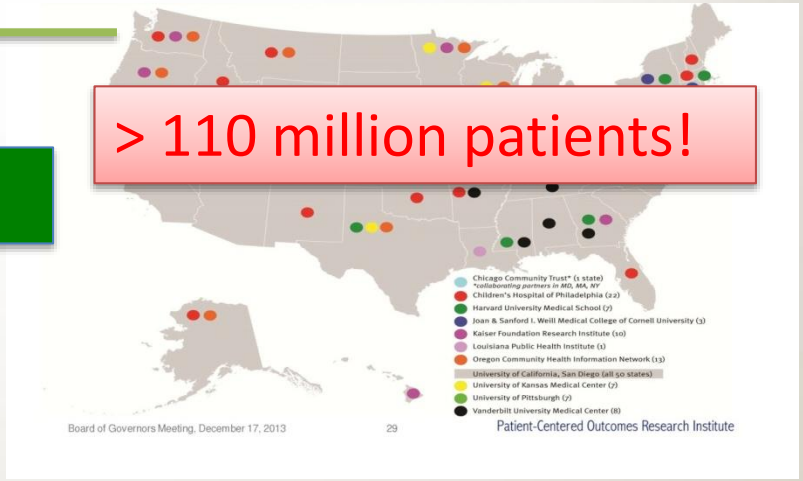


1. Queries and Analytic Software Packages from PCORI

2. CDRN returns Counts and Aggregate resulting data

PopMedNet

PCORNet



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PCORI Common Data Model V 3.0

CONDITION v2.0
A condition represents a patient's diagnosed and self-reported health conditions and diseases. The patient's medical history and current state may both be represented.

DEATH v3.0
Reported mortality information for patients.

DEATH_CAUSE v3.0
The individual causes associated with a reported death.

DEMOGRAPHIC v1.0
Demographics record the direct attributes of individual patients.

DIAGNOSIS v1.0
Diagnosis codes indicate the results of diagnostic processes and medical coding within healthcare delivery.

DISPENSING v2.0
Outpatient pharmacy dispensing, such as prescriptions filled through a neighborhood pharmacy with a claim paid by an insurer. Outpatient dispensing is not commonly captured within healthcare systems.

ENROLLMENT v1.0
Enrollment is a concept that defines a period of time during which all medically-attended events are expected to be observed. This concept is often insurance-based, but other methods of defining enrollment are possible.

ENCOUNTER v1.0
Encounters are interactions between patients and providers within the context of healthcare delivery.

HARVEST v3.0
Attributes associated with the specific PCORnet datamart implementation

LAB_RESULT_CM v2.0
Laboratory result Common Measures (CM) use specific types of quantitative and qualitative measurements from blood and other body specimens. These standardized measures are defined in the same way across all PCORnet networks.

PCORNET_TRIAL v3.0
Patients who are enrolled in PCORnet clinical trials.

PRESCRIBING v3.0
Provider orders for medication dispensing and/or administration.

PRO_CM v2.0
Patient-Reported Outcome (PRO) Common Measures (CM) are standardized measures that are defined in the same way across all PCORnet networks. Each measure is recorded at the individual item level: an individual question/statement, paired with its standardized response options.

PROCEDURES v1.0
Procedure codes indicate the discreet medical interventions and diagnostic testing, such as surgical procedures, administered within healthcare delivery.

VITAL v1.0
Vital signs (such as height, weight, and blood pressure) directly measure an individual's current state of attributes.

PCORI Common Data Model V 3.0

Site	Sites in CDM	Patients in CDM	Encounters in CDM	CDM Dates	Production CDM Refresh Rate*
Vanderbilt	Vanderbilt University Health System	1,683,921	27,164,268	1/09 - 03/17	Quarterly update
VHAN	Williamson Medical Center, Maury Regional Medical Center, West TN Health	386,015	1,305,116	12/13 - 03/16	Quarterly update
Greenway Health	952 sites	16,754,670	103,984,550	1/10 - 12/15	Quarterly Update
UNC at Chapel Hill	UNC Health Care System	2,138,696	20,817,024	6/04 – 4/17	Quarterly update
Duke University	Duke University	2,254,461	39,788,694	1/05 – 3/17	Quarterly update
HSSC	Greenville Health System (GHS), MUSC Health (MUSC), Palmetto Health (PH), and Spartanburg Regional Healthcare System (SRHS)	3,105,315	31,837,251	SRHS: 1/11 – 12/16 PH: 1/11-12/16 MUSC: 1/07 – 12/16	Quarterly update
Meharry Medical College	Meharry Medical College and Nashville General Hospital	137,147	751,870	1/04 – 04/17	Quarterly update

* Production tables are updated after data characterizations have been approved by the Coordinating Center

Additional Linkage for "Complete" Data

TN State Health Data

- Includes statewide hospital discharge data and vital statistics(death) data. Approved for 1998-2015 data
- Agreements in place; Will purchase 2015 once ready
- Currently have 2011-2014 data, Linkage in process!

Tenncare Data

- Includes health claims data derived from approx. 1,480,430 individuals covered under the states Medicate coverage
- Agreements in place, linkage/pipeline in process of being built
- Received Data, Linkage in process!

CMS Data (RESDAC, CMMI data)

- Reuse application in process – waiting on IRB approval and original DUA extension from CMS
- CDRN-wide linkage plan in development

Vanderbilt Health Plan (Aetna)

- Includes health claims data derived from approx. 19,600 employees and dependents covered. Years 2011-2016 available
- Agreements in place, data linkages in process

Linkage to NC BC/BS Data and NC Medicaid Data

- Data Use Agreements complete;
- Linkage approved on a case by case basis

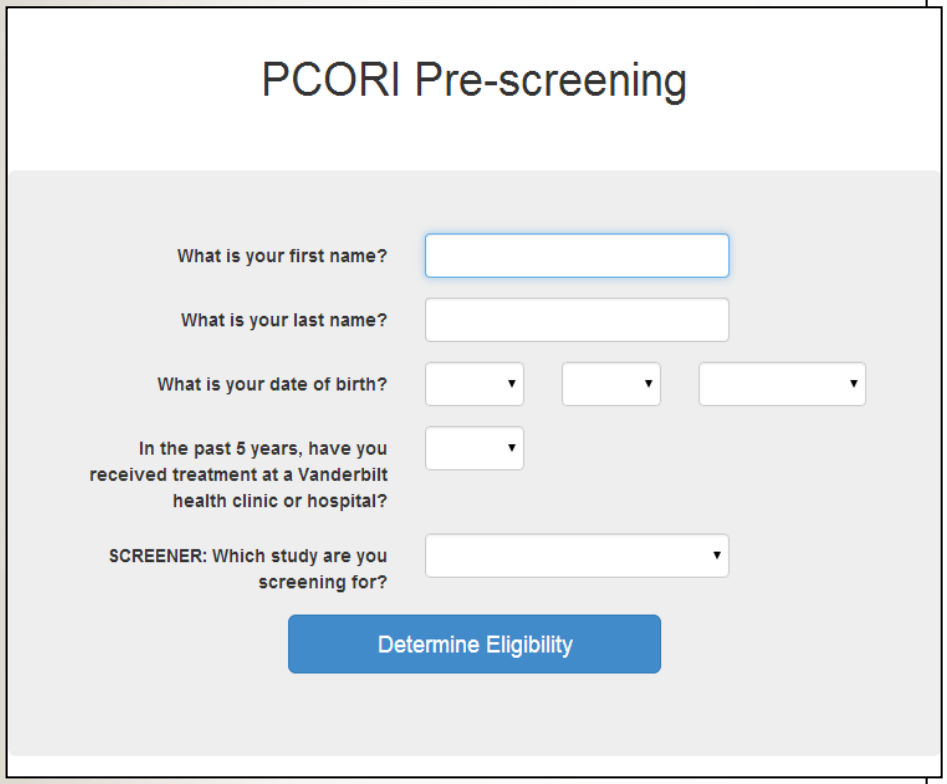
Linkage to SC Claims Data

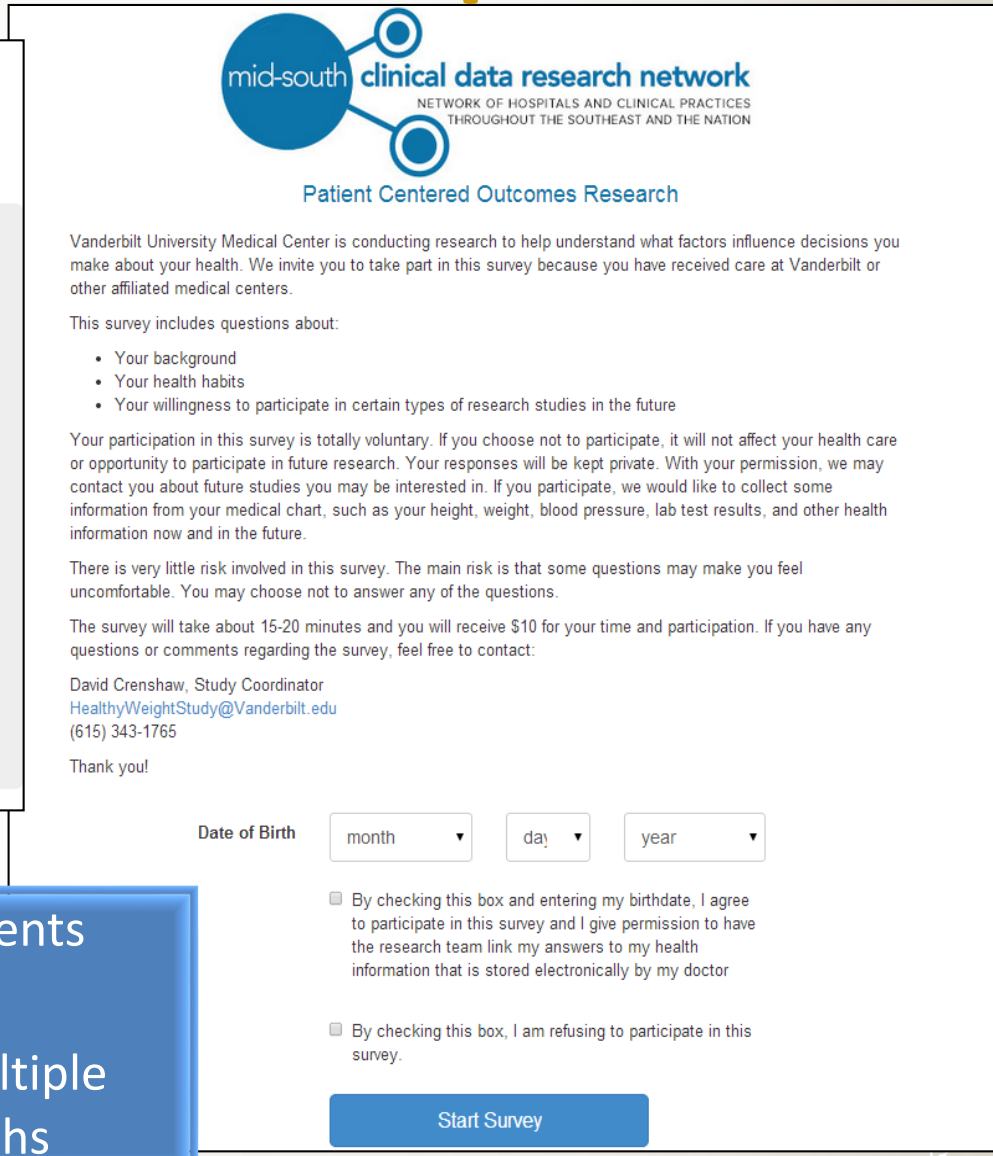
- Data Use Agreement Complete
- Linkages available on a per project basis

Novel Informatics Tools

- Tools for quickly running queries and analyzing electronic health data
- Tools for identifying and contacting patients
  - Email, Text, Phone (> 400K emails at VUMC)
  - My Research at Vanderbilt (~30K)
  - Epic MyChart (MUSC)
- New electronic consent process
- Expanded survey tools for collection of patient reported outcomes (via web/mobile platforms, automated phone, embedded video/audio, etc.)
- Integration of PROMIS measures into REDCAP
- Electronic payment processes for study participation
- Potential integration of patient survey data into the EHR for clinical use
- Expansion of clinical decision support tools

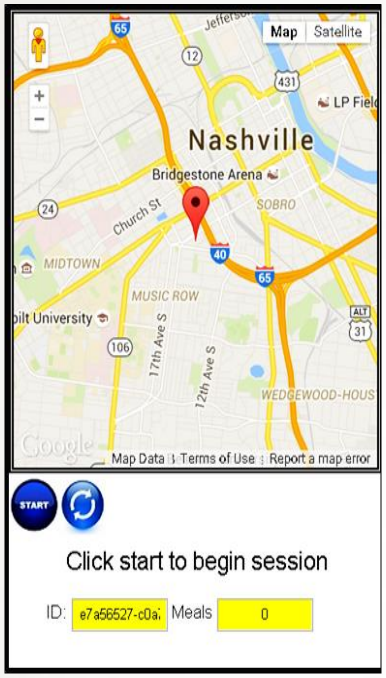
Weight Cohort Example

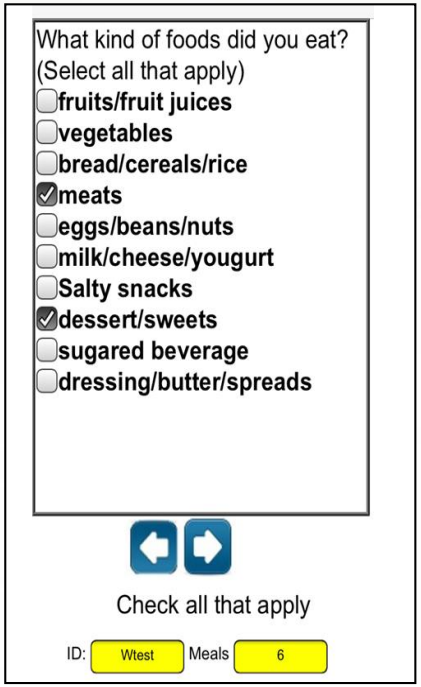


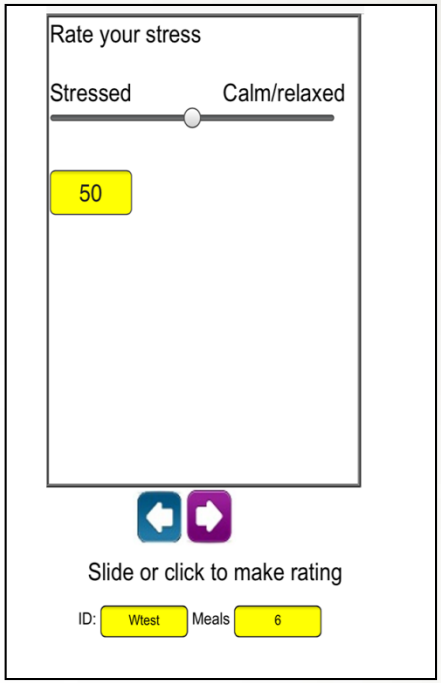


- Email blast to >10,000 Vanderbilt patients with over 30% response rate!
- Surveyed > 10,000 patients across multiple health systems/clinic sites in < 6 months

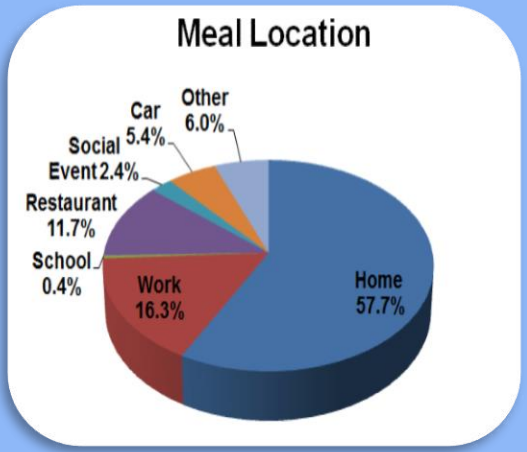
Mobile Data Collection







- 396 enrolled participants
- 11,189 meals
- Mean of 28.3 (17.6) meals/person



VANDERE
ME

BMI by Eating Clusters

	Adjusted β	95% CI	P-value
Healthy	Ref	Ref	Ref
Healthy Emotional	1.9	1.5, 2.3	<0.001
Unhealthy	2.4	2.0, 2.8	<0.001
Unhealthy Emotional	5.1	4.7, 5.6	<0.001

Adjusted for age, gender, race/ethnicity, income, and physical activity.

Heerman, B. *J Nutr Educ Behav.* 2017

Identifying Eligible CHD Patients

- Case 1: 2 outpatient visits billed for MI or CHD
  - N=27,194
- Case 2: 1 or more revascularization procedure codes
  - N=3,637 additional
- 26,343 of 30,831 pts (85.4%) had encounter in last 2 yrs

	CHD Disease Positive	CHD Disease Negative	TOTALS
CHD algorithm detected	192	3	195
CHD algorithm NOT detected	11	264	275
TOTALS	203	267	470

Positive Predictive Value	192/195	98.5%
Negative Predictive Value	264/275	96.0%
Sensitivity (true positives)	192/203	**94.6%**
Specificity (true negatives)	264/267	**98.9%**

Available in Phenotype Knowledge Base:

Roumie CL, Shirey-Rice J, Kripalani S. MidSouth CDRN – Coronary Heart Disease algorithm. PheKB (a knowledgebase for discovering phenotypes from electronic health records). Available at: https://phekb.org/phenotype/midsouth-cdrn-coronary-heart-disease-algorithm

CHD "Personome"

70% married
12% divorced
12% widowed
21% live alone

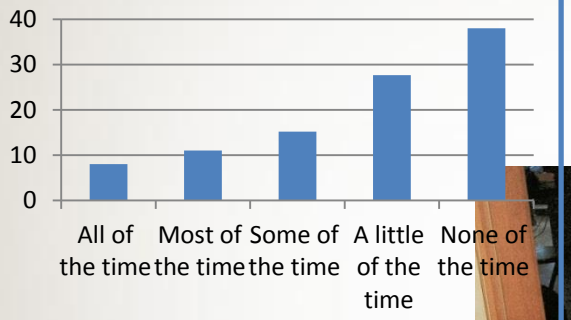
26% missed their meds at least once in the last week

9% not high school graduate

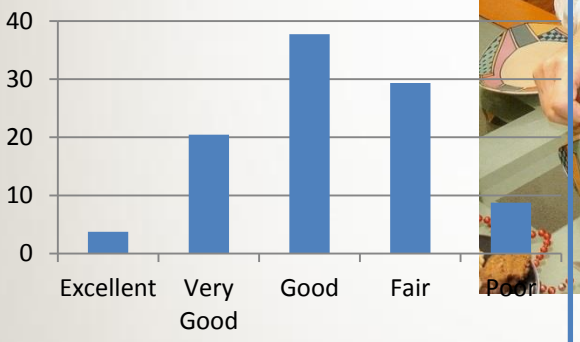
35% make ≤ $35k

17% disabled

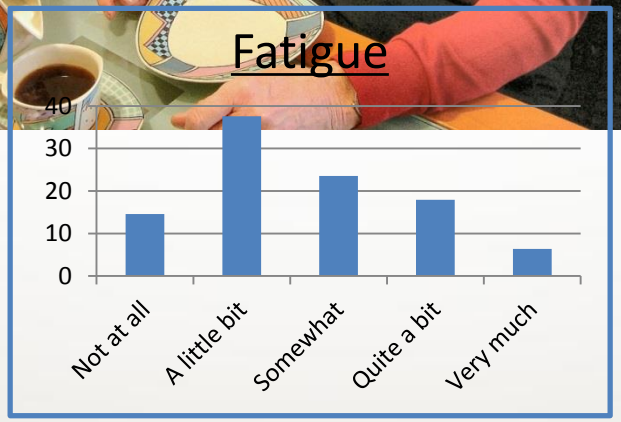
Emotional Support



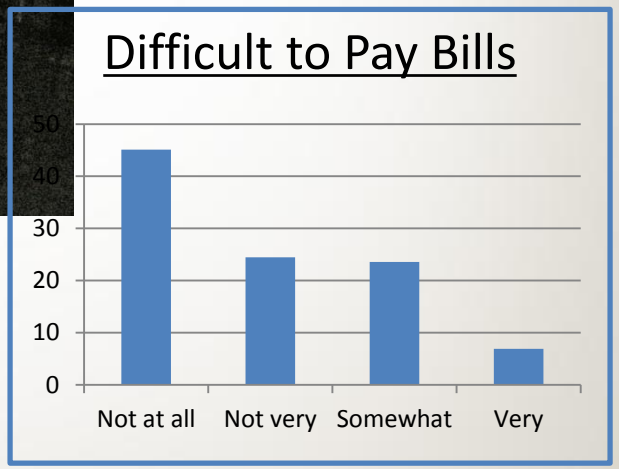
Self-rated health



Fatigue



Difficult to Pay Bills



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Response Rates for Different Recruitment Approaches

	Face-to-face	Phone call	Letter with URL	Mailed survey	Email			
					Email from physician	Email from researcher	Research Match	Two-step screening
Eligible	2,443	874	1,430	1,276	23,572	33,733	447	12,468
Consented	2,305	331	520	370	1,451	5,008	340	3,845
Completed	2,248	320	504	369	1,356	4,383	335	3,682
Response rate	94.3%	37.8%	36.3%	28.9%	6.1%	14.8%	76.0%	30.8%

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Heerman, *Contemporary Clinical Trials*, 2017

AR-POWER Collaboration

- ~21K emailed (MRAV and Clinics) and 256 patients joined AR-POWER

Tue 6/27/2017 1:26 PM

myresearch@vanderbilt.edu

MyResearch: Join other patients in the search for a cure

To [redacted]

If there are problems with how this message is displayed, click here to view it in a web browser.

Message ArthritisPower_flyer.pdf (9 MB)

Please disregard if you have already joined the ArthritisPower network.
Hello,

In a survey sent to My Health at Vanderbilt users you agreed to be contacted directly to receive information about research studies. Below is a description of a
possibly match your health profile.

We are excited to introduce you to ArthritisPower, a new online resource and smart phone app for patients with arthritis and other bone, joint and autoimmune

This resource is free and allows you to help keep track of your symptoms and take control of your condition with your computer or smart phone.

In addition, you can volunteer to participate in this patient research network and join in studies to learn about the safety and effectiveness of various medication
exercise and meditation. If you decide to join ArthritisPower, you can elect to share your Vanderbilt electronic health records with the registry for scientific stu

By joining ArthritisPower you will be joining thousands of others and give patients a much needed voice in comparing treatments to each other as well as ident
cure.

ArthritisPower is the first ever patient centered research registry for arthritis and related conditions and is completely voluntary. If you decide not to participate,
We hope you'll consider downloading this app or using it online. Visit www.ArthritisPower.org or see the attached flyer to learn more.

Please let your rheumatologist know if you have any questions.

Best wishes,

Leslie J. Crofford, MD
Professor of Medicine
Director, Division of Rheumatology & Immunology

THE POWER IS YOURS!

Join the First Ever Patient-Led, Patient-Centered Research Database for Arthritis Patients

ARTHRITISPOWER™
Research by patients, for patients.
A CreakyJoints® initiative.

What is ARTHRITISPOWER? ARTHRITISPOWER is the first ever patient-led, patient-generated, patient-centered research registry for arthritis. Using the web-based and mobile application ("app"), patients from around the world are tracking symptoms to support future research to compare treatments, identify new treatments and, perhaps, find elusive cures.

Who's it for? ARTHRITISPOWER is open to patients living with arthritis and other related conditions of the joints, bones or skin, such as:

Ankylosing Spondylitis
Fibromyalgia
Gout
Crohn's-related (Enteropathic) Arthritis
Juvenile Idiopathic Arthritis
Lupus
Myositis (Inflammation of the Muscles)
Osteoarthritis
Osteoporosis/Osteopenia/Low Bone Mineral Density
Psoriasis
Psoriatic Arthritis
Rheumatoid Arthritis
Scleroderma (Systemic Sclerosis)

How Do I Get Started? 1. Visit the ARTHRITISPOWER.org website or download the mobile app. 2. Read and sign the consent. 3. Fill out the registration questionnaire. 4. Start tracking!

What does patient-centered mean? Patient-centered research means investigating topics that are important to patients and helping them make informed health care decisions. ARTHRITISPOWER is led by a committee of Patient Governors who help identify research needs for study development and prioritize research requests from the CreakyJoints patient community around the world. Different studies will be listed in the ARTHRITISPOWER app and each patient can decide when and how to participate.

How will collected data be used? Registered patients will enter their personal data into the ARTHRITISPOWER mobile application or web-based equivalent. The information you share will be securely stored and used by university-based researchers and the ARTHRITISPOWER patient community. Research results will be shared on the ARTHRITISPOWER app.

Who created Arthritis Power? CreakyJoints, the online, non-profit, patient support community for arthritis patients with over 80,000 members created ARTHRITISPOWER. Technical support and human subjects protection oversight are provided by the University of Alabama at Birmingham.

TRACK, SHARE, SEND & DISCUSS: ARTHRITISPOWER participants can easily share and send their personal health information to their doctors via the "My Reports" function in the app. An emailed report lists current medications and selected symptoms data. Empower yourself to lead conversations with your healthcare team!

JOIN ARTHRITISPOWER TODAY: www.ARTHRITISPOWER.org

To learn more about CreakyJoints, an online arthritis community supporting more than 80,000 members by providing support, blogs, research updates and education, innovative advocacy and global research projects, visit www.CreakyJoints.org.

Stakeholder Engagement

- **Governance:**

•Co-Investigator – 1 member

•Stakeholders at Oversight Committee – 2 members

•Stakeholder Advisory Council– 4 members (3 VU, 1 Carolinas)

- **Stakeholder input:**

•Surveys

  – 480 Providers - (30% racial/ethnic minorities, 16% Community Health Centers)

  – >5,000 consumers – completed

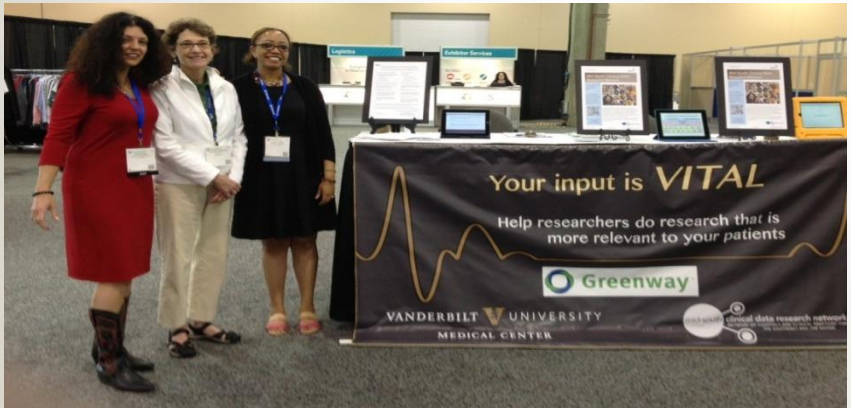
•Provider Interviews

  – 59 (44.1% Physician)

•Community Engagement studios – 58 stakeholders

- **Proposal Review:**

•Stakeholder Engagement Review Process

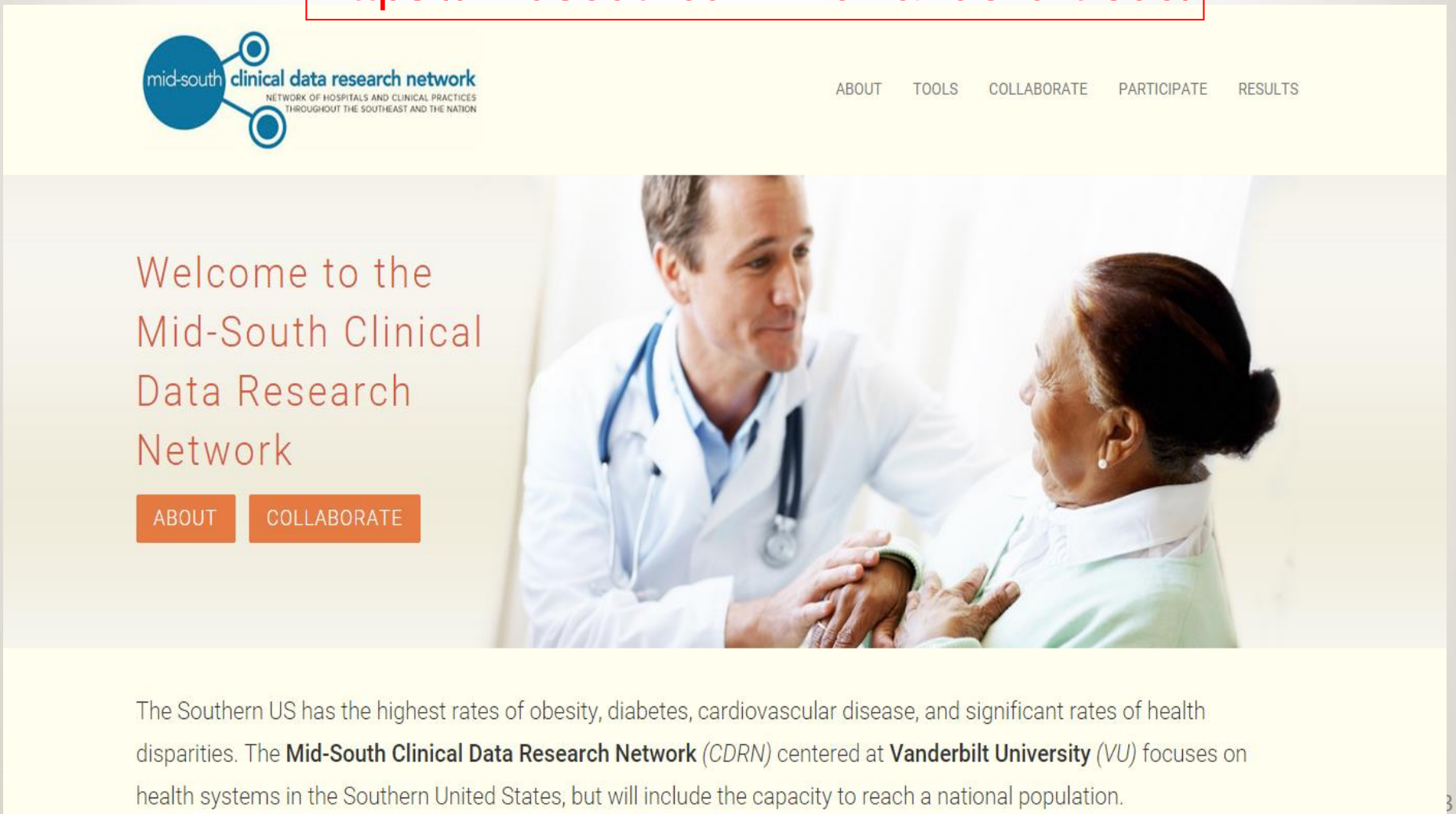


Regulatory Efficiencies

- **SMART IRB (Central IRB)**
  - 100% of Mid-South sites have signed on
- **Data Sharing Agreements: DSA 2.o**
  - Includes Indemnification/Liability options, network participation institutional/state requirements
  - All sites have signed the DSA
- **Contract Share**
  - Shared templating for contracts

Process for accessing resources

https://midsouthcdrn.mc.vanderbilt.edu/



PCORnet Examples

- Preliminary data from national weight cohort
- ADAPTABLE pragmatic clinical trial

Weight Cohort across PCORnet

		All DataMarts
Adult	2010-2014	10,174,030
	2014	5,043,643
	2013	4,365,744
	2012	3,480,730
	2011	2,271,557
	2010	1,755,450
Child	2010-2014	4,366,777
	2014	1,665,083
	2013	1,483,721
	2012	1,242,143
	2011	884,348
	2010	705,056

NHANES 2011-2012: 5,211

NHANES 2011-2012: 3,999

PCORnet Weight Cohorts vs. NHANES

	All DataMarts			
	PCORnet Adults	NHANES Adults	PCORnet Children	NHANES Children
Underweight	1.8%	1.7%		
Normal weight	29.2%	29.0%	67.2%	68.0%
Overweight	31.9%	34.0%	15.1%	15.0%
Obesity	29.6%	35.0%	17.7%	17.0%
Severe Obesity	7.6%	6.0%		

ADAPTABLE Study Design

Patients with known ASCVD + ≥ 1 "enrichment factor"*

Identified through EHR (computable phenotype) by CDRNs
(PPRN patients that are already a part of a CDRN are eligible to participate.)

↓

Patients contacted with trial information and link to e-consent;†
Treatment assignment will be provided directly to patient

↓

ASA 81 mg QD | ASA 325 mg QD

↓

Electronic follow-up: Every 3–6 months
Supplemented with EHR/CDM/claims data

↓

Duration: Enrollment over 24 months;
maximum follow-up of 30 months

Primary endpoint:
Composite of all-cause mortality, hospitalization for MI, or hospitalization for stroke

Primary safety endpoint:
Hospitalization for major bleeding

† Participants without internet access will be consented and followed via a parallel system.

Disrupting the Norm
Traditional Trials vs. ADAPTABLE

	Traditional	ADAPTABLE
I/E Criteria Reviewed	Sample via CRA Visit	CDM
Representative Cohort	Narrow	Broad
Consent	Facilitated	Patient Directed
Comprehension Tested	No	Yes
Format	Paper	e-consent
Data Collection	Patient Reported	Patient Reported
	Site Recorded	CDM
Source Documents	Only seen by Site	Received via CDM
Endpoint Adjudication	Yes	CDM, EHR data
Patient Involvement	Participants Only	Protocol design, Committee, Analyses, Dissemination
Costs	+++++	+

Adaptable
The Aspirin Study

Presented in English
En Espanol

A TEXT SIZE A

Let's get started!

Thank you for taking the time to find out more details about the ADAPTABLE aspirin study.
With your help, we hope to find out what is the right dose of aspirin for people with heart disease.

Got a code?

Please enter in the special code that was included in your invitation:

AX3BN

ENTER

No code? No problem!

You can still learn more about this study even if you have not been asked to participate.

CONTINUE

Already have a profile? Login

Adaptable
The Aspirin Study

TEXT SIZE A

There are 5 steps to join the study!

The time on each card is an estimate of
how long it will take you to complete each section.
There are no time limits, so please go at your own pace.

Watch
the ADAPTABLE short video

5 min

Read
more details about participating in ADAPTABLE

15 min

Answer
a few questions about the study

5 min

Join
the ADAPTABLE study

3 min

Inform
us about your current health

5 min

LET'S GET STARTED

Web-Based, Electronic Informed Consent

- Text and video review of the consent is completed on the web portal
- Simplified common consent form with selected local adaptations
- Focused questions to confirm patient comprehension for informed consent and eligibility for randomization after consent is obtained
- Direct patient feedback and user testing for the development of the consent form and process as well as the comprehension questions

Adaptable
The Aspirin Study

Watch | Read 15 MIN. | Answer 5 MIN. | Join 3 MIN. | Inform 5 MIN.

You can re-watch the video at any time by clicking on the camera icon above.

TEXT SIZE A

ADAPTABLE Information

Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE)

We are asking you to join a research study called ADAPTABLE. The information below explains the study so you can decide if you want to take part or not. Please read it carefully and take all the time you need to decide. Feel free to talk it over with your family, friends, and doctor. If there is anything you do not understand, be sure to ask questions.

WHY IS THIS STUDY BEING DONE?

For more than 40 years, doctors have been telling patients with heart disease to take aspirin. For these patients, taking aspirin every day can lower the risk of heart attacks and strokes.

Millions of Americans who have heart disease already take either regular (325 mg) or low-dose (81 mg) aspirin. Many studies have shown that both doses work and both are generally safe. The most common side effect of aspirin is an upset stomach. Aspirin can also make you bleed more easily. In rare cases (about 5 in 1,000 people), it can cause dangerous bleeding in the stomach, brain, or other places.

Even though both doses of aspirin are widely used, no one knows which is better. Regular aspirin has a higher risk of bleeding than low-dose aspirin. But no one knows if low-dose aspirin is both safer and works just as well as regular aspirin to prevent heart and blood vessel problems.

The goal of ADAPTABLE is to try to find out which dose of aspirin is better for patients like you who have heart disease. Patients who join this study will take either low-dose or regular aspirin every day. That way, we can learn which is better in terms of reducing the risk of heart attacks, strokes, bleeding, and death.

We expect 20,000 patients [illegible] will take part in ADAPTABLE.

Please scroll to see all content

Adaptable
The Aspirin Study

Watch ✓ | Read ✓ | Answer 5 MIN. | Join 3 MIN. | Inform 5 MIN.

Question 1 of 6

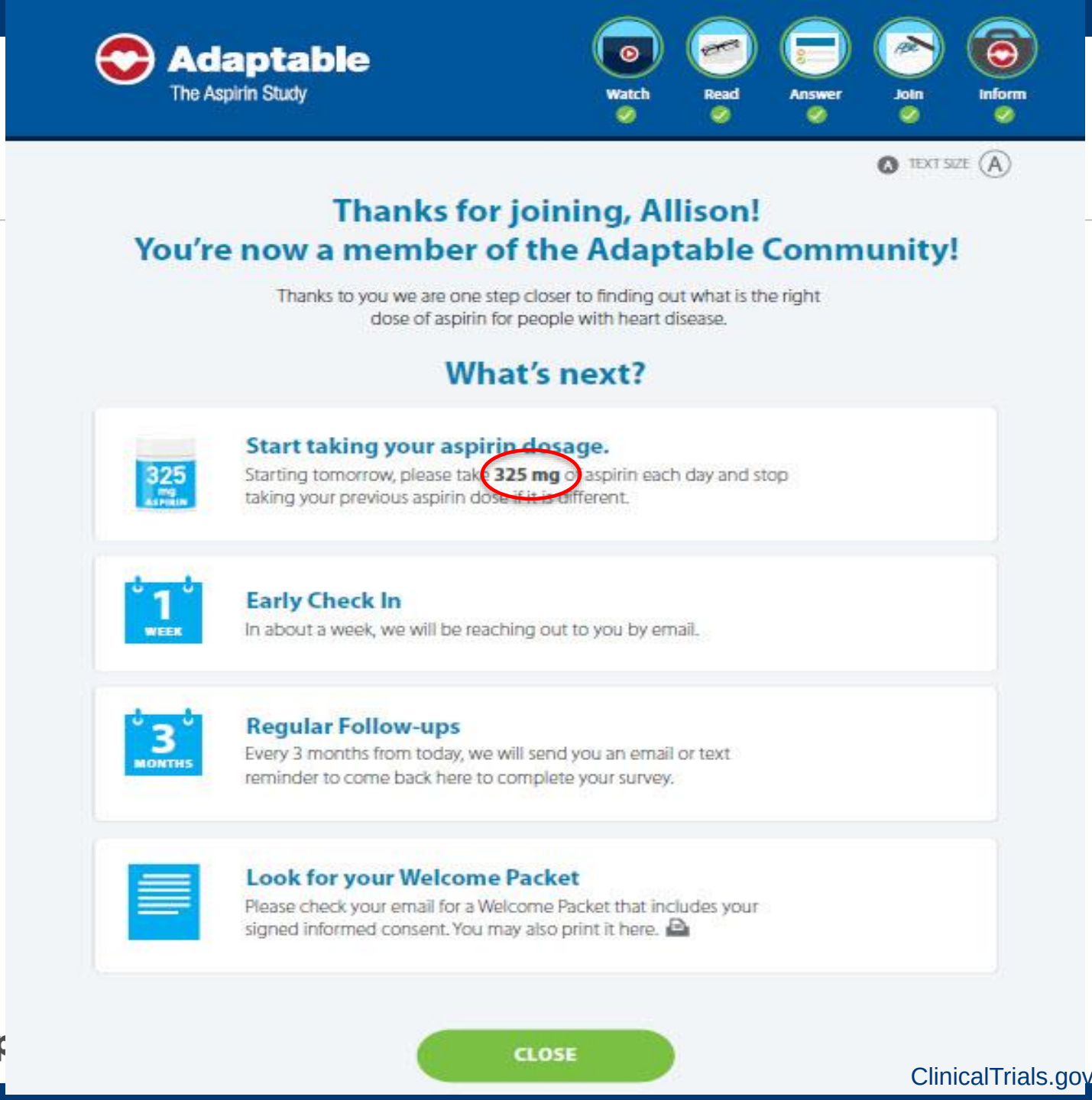
TEXT SIZE A

ADAPTABLE is a research study. The main reason for doing this study is because, for patients who have heart disease, no one knows:

- ○ whether taking aspirin has any side effects.
- ○ which of two commonly-used doses of aspirin is better.
- ○ if a new, experimental alternative to aspirin is safe.

You must select one answer to continue.

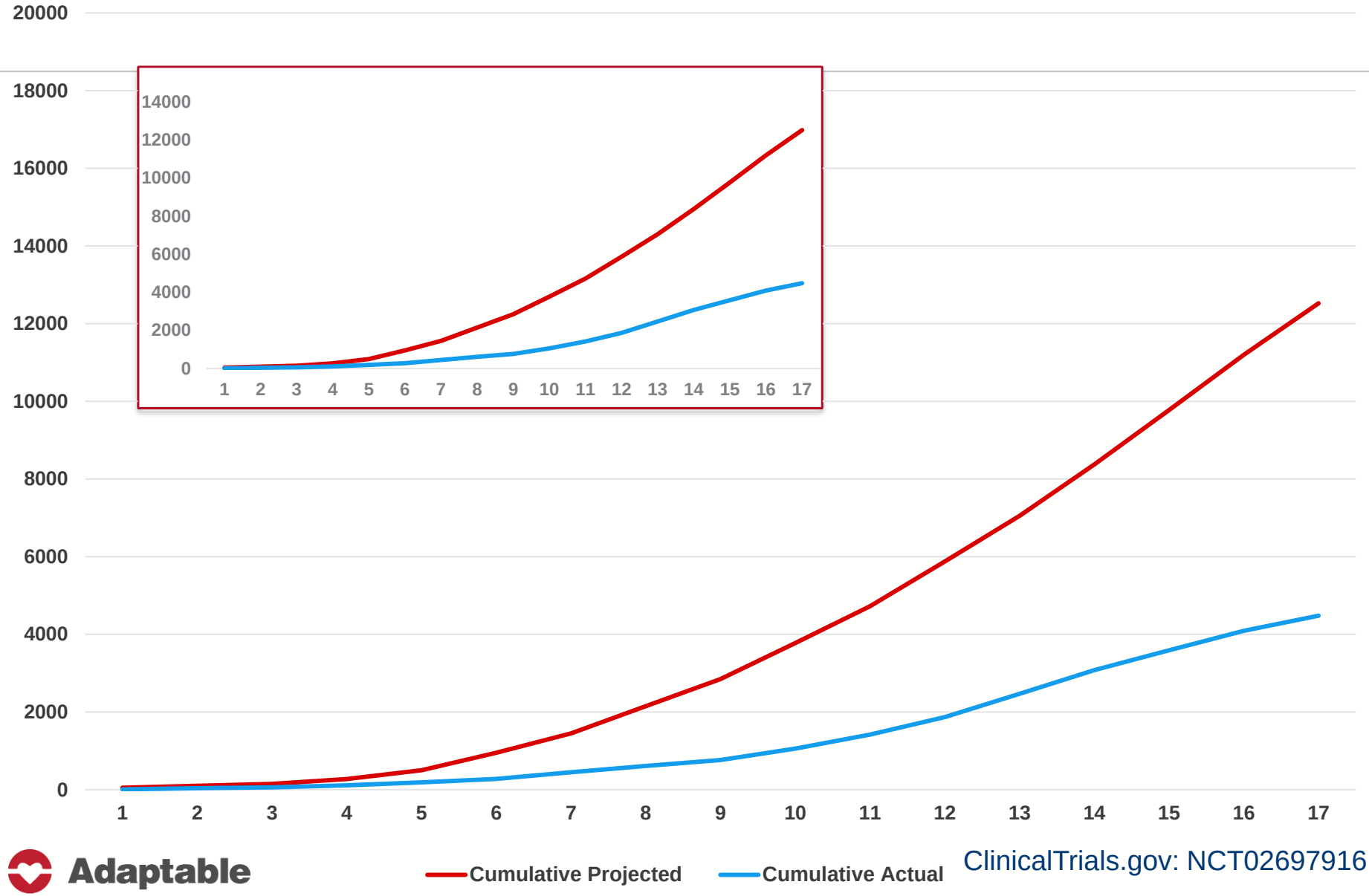
SUBMIT



Adap

ClinicalTrials.gov: NCT02697916

ADAPTABLE Enrollment



Adaptable

ClinicalTrials.gov: NCT02697916

Site Approach & Enrollment Update (8/28)

CDRN	Site	Total Number Eligible	Total Number Approached	% of Eligible Approached	Golden Tickets Entered	% Golden Tickets entered per Approached	Total Enrolled	# Non-internet Enrolled	% Enrolled Per Approached	% Enrolled Per Golden Ticket Entered	Enrolled last week
MidSouth	Vanderbilt	22,271	17,970	81%	1,896	11%	992	49	6%	52%	23
Mid-South	Duke	20,127	2,138	11%	738	35%	561	111	26%	76%	13
PaTH	UPMC	13,879	9,447	68%	1,172	12%	370	0	4%	32%	0
REACHnet	Ochsner	13,560	8,473	62%	756	9%	294	63	3%	39%	6
OneFlorida	U of Florida	29,738	4,948	17%	371	7%	279	50	6%	75%	10
NYC-CDRN	Montefiore	47,383	2,603	5%	261	10%	210	83	8%	80%	4
PaTH	Penn St	5,246	5,237	100%	567	11%	195	0	4%	34%	6
GPC	Marshfield Clinic	14,949	9,980	67%	395	4%	179	0	2%	45%	6
GPC	Iowa	11,391	6,696	59%	350	5%	175	28	3%	50%	3
PaTH	Utah	6,054	5,954	98%	380	6%	174	17	3%	46%	2
Mid-South	UNC	5,204	2,107	40%	249	12%	131	28	6%	53%	13
GPC	KUMC	4,269	4,024	94%	289	7%	128	0	3%	44%	0
CAPriCORN	U of Chicago	5,446	907	17%	131	14%	123	80	14%	94%	4
GPC	MCW	12,220	6,108	50%	363	6%	123	0	2%	34%	3
CAPriCORN	Northwestern	6,697	6,746	101%	226	3%	111	5	2%	49%	1
NYC-CDRN	Weill Cornell	5,856	1,282	22%	251	20%	97	4	8%	39%	6
pScanner	UCLA	15,669	5,229	33%	160	3%	82	3	2%	51%	0
REACHnet	BSW	3,958	2,541	64%	165	6%	56	7	2%	34%	2
CAPriCORN	Rush	8,826	2,904	33%	90	3%	45	4	2%	50%	1
PaTH	Temple	6,522	4,989	76%	157	3%	36	9	1%	23%	1
NYC-CDRN	NYU	31,795	1,126	4%	155	14%	34	1	3%	22%	1
GPC	Nebraska	3,475	1,247	36%	59	5%	26	0	2%	44%	0
NYC-CDRN	Mt Sinai	15,832	643	4%	66	10%	22	7	3%	33%	0
GPC	UTSW	2,459	522	21%	32	6%	19	0	4%	59%	1
GPC	Missouri	1,204	617	51%	32	5%	11	0	2%	34%	0
REACHnet	Tulane	771	124	16%	5	4%	5	2	4%	100%	0
PaTH	Johns Hopkins	23,935	5	0%	4	80%	1	0	20%	25%	0
TOTAL		**338,736**	**114,567**	**34%**	**9,320**	**8%**	**4,479**	**551**	**4%**	**48%**	**106**

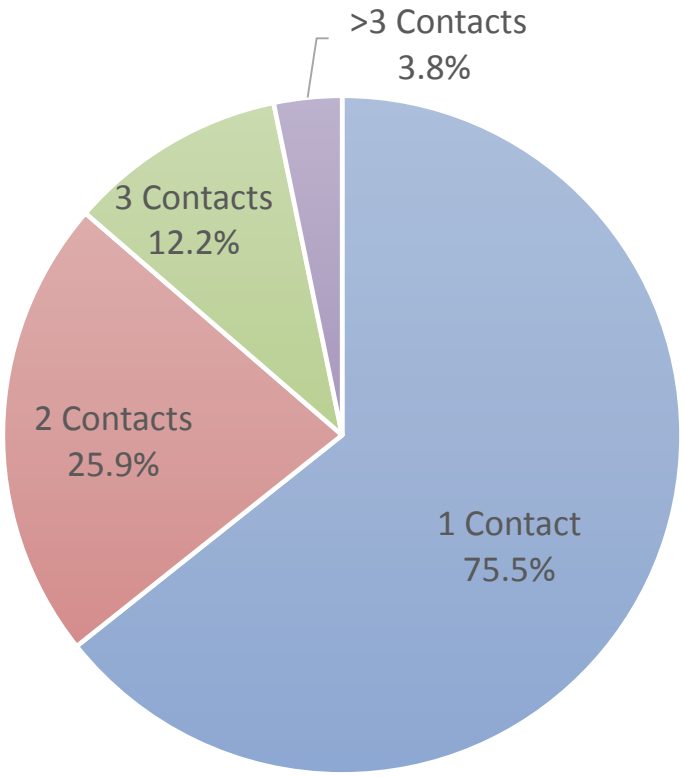
Adaptable

Site Enrollment Average (8/28)

CDRN	Site	Site Activated	Started Enrollment	Total Enrolled	Enrollment Rate/Month
Mid-South	Duke	11/9/2016	November	561	62.3
Mid-South	Vanderbilt	4/18/2016	April	992	62.0
Mid-South	UNC	1/13/2017	April	131	32.8
OneFlorida	U of Florida	11/1/2016	November	279	31.0
PaTH	UPMC	7/18/2016	August	370	30.8
GPC	Marshfield Clinic	11/1/2016	February	179	29.8
NYC-CDRN	Montefiore	11/9/2016	November	210	23.3
CAPriCORN	U of Chicago	2/16/2017	February	123	20.5
PaTH	Penn State	9/23/2016	October	195	19.5
NYC-CDRN	Weill Cornell	3/8/2017	March	97	19.4
REACHnet	Ochsner	4/18/2016	April	294	18.4
GPC	MCW	11/9/2016	January	123	17.6
PaTH	Utah	9/23/2016	October	174	17.4
GPC	Iowa	7/18/2016	August	175	14.6
GPC	KUMC	11/1/2016	November	128	14.2
CAPriCORN	Northwestern	8/30/2016	September	111	10.1
pScanner	UCLA	11/7/2016	November	82	9.1
CAPriCORN	Rush	9/19/2016	February	45	7.5
GPC	Nebraska	12/21/2016	April	26	6.5
REACHnet	BSW	9/19/2016	October	56	5.6
NYC-CDRN	Mt Sinai	12/21/2016	March	22	4.4
NYC-CDRN	NYU	11/1/2016	November	34	3.8
GPC	UTSW	11/1/2016	March	19	3.8
PaTH	Temple	9/23/2016	October	36	3.6
GPC	Missouri	12/21/2016	March	11	2.2
PaTH	Johns Hopkins	8/31/2016	June	1	0.5
REACHnet	Tulane	8/30/2016	October	5	0.5

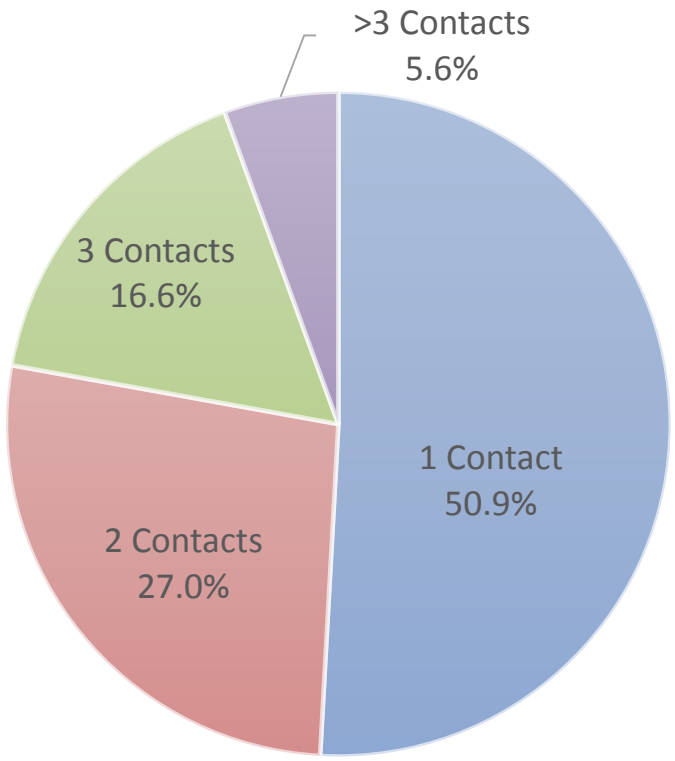
Initial Approach Metrics

Contacts Metrics
Approached Participants



41,315 Total Approached

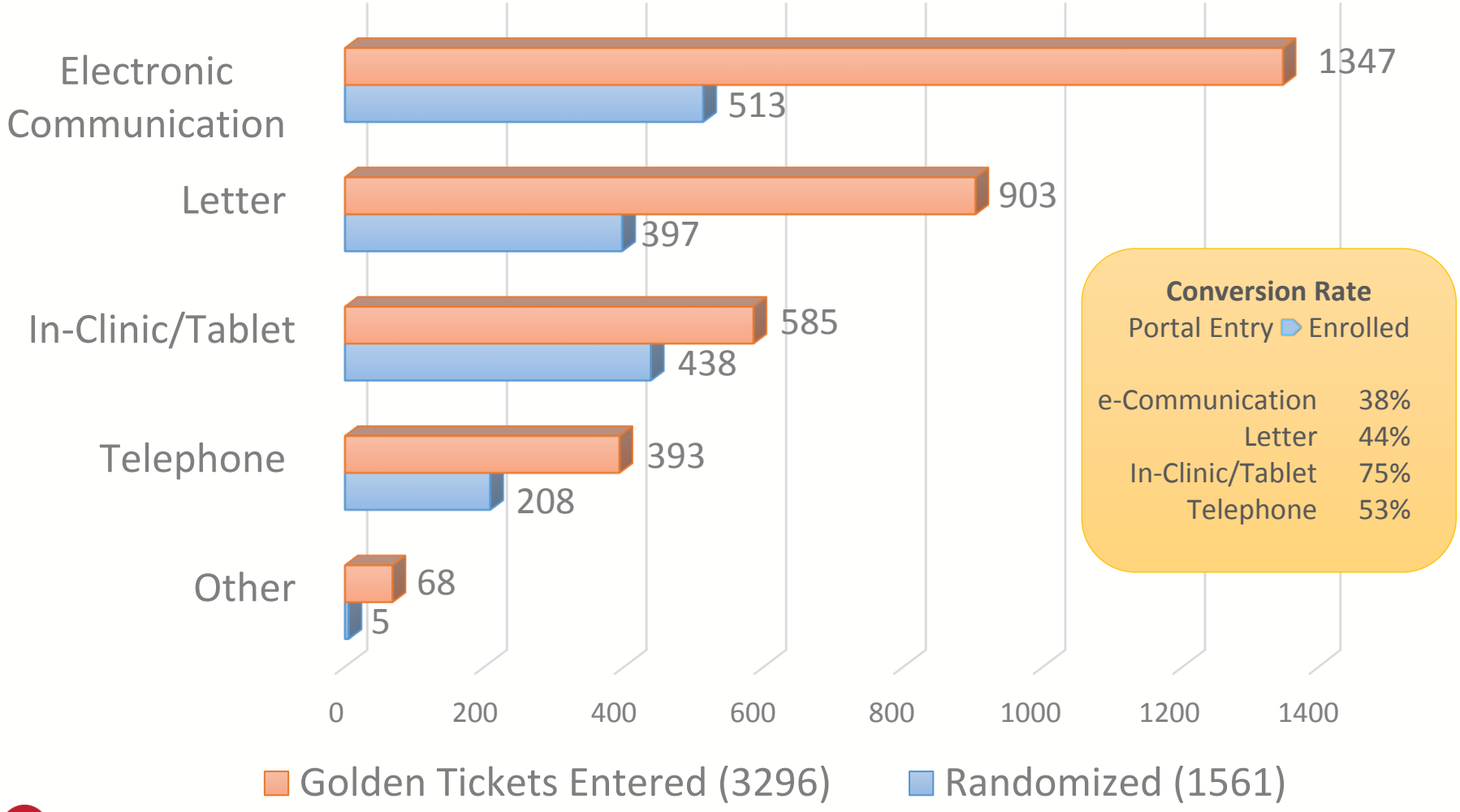
Contact Metrics
Randomized Participants



1,313 Total Randomized

Adaptable

Invitation Methods
Golden Tickets Entered vs Randomized

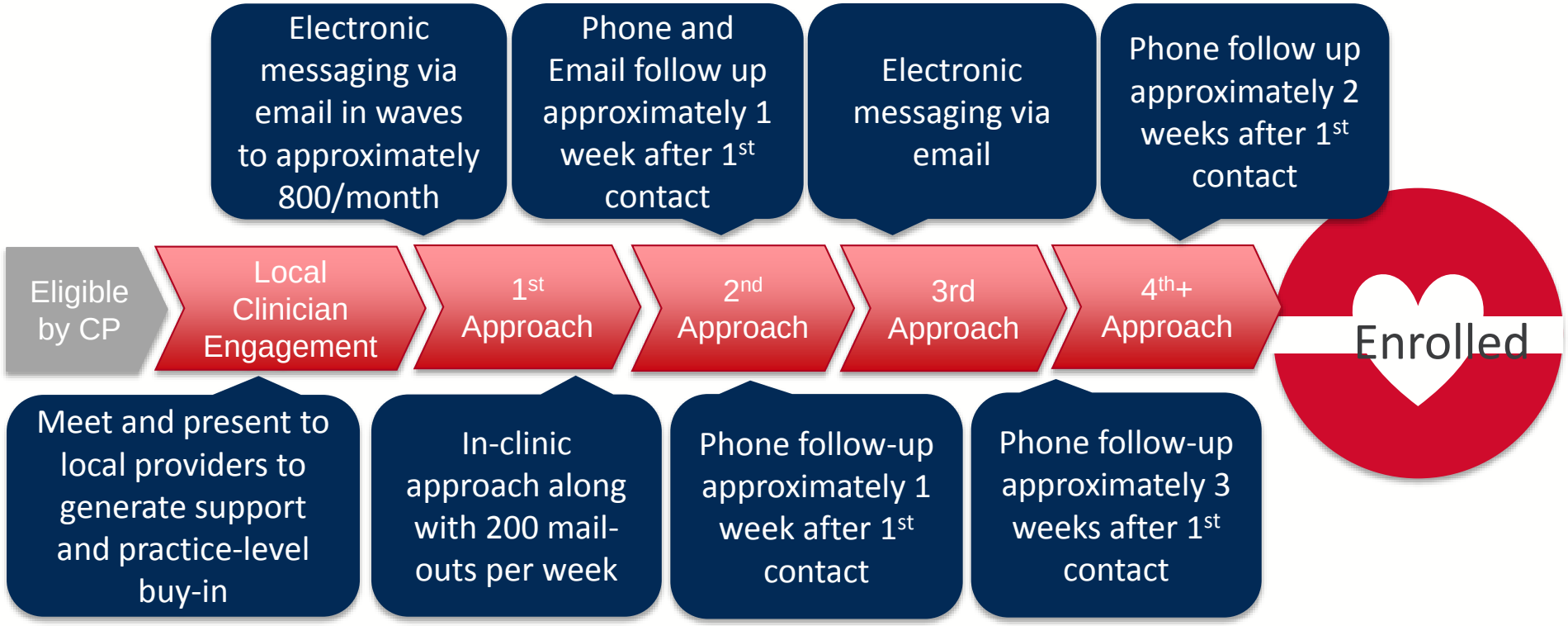


Adaptable

Phase 2: Recruitment Strategies (Mid-South)

Vanderbilt	Duke	UNC
18,440	19,902	5,204

*CP2 eligibility numbers as of Mar 1, 2017

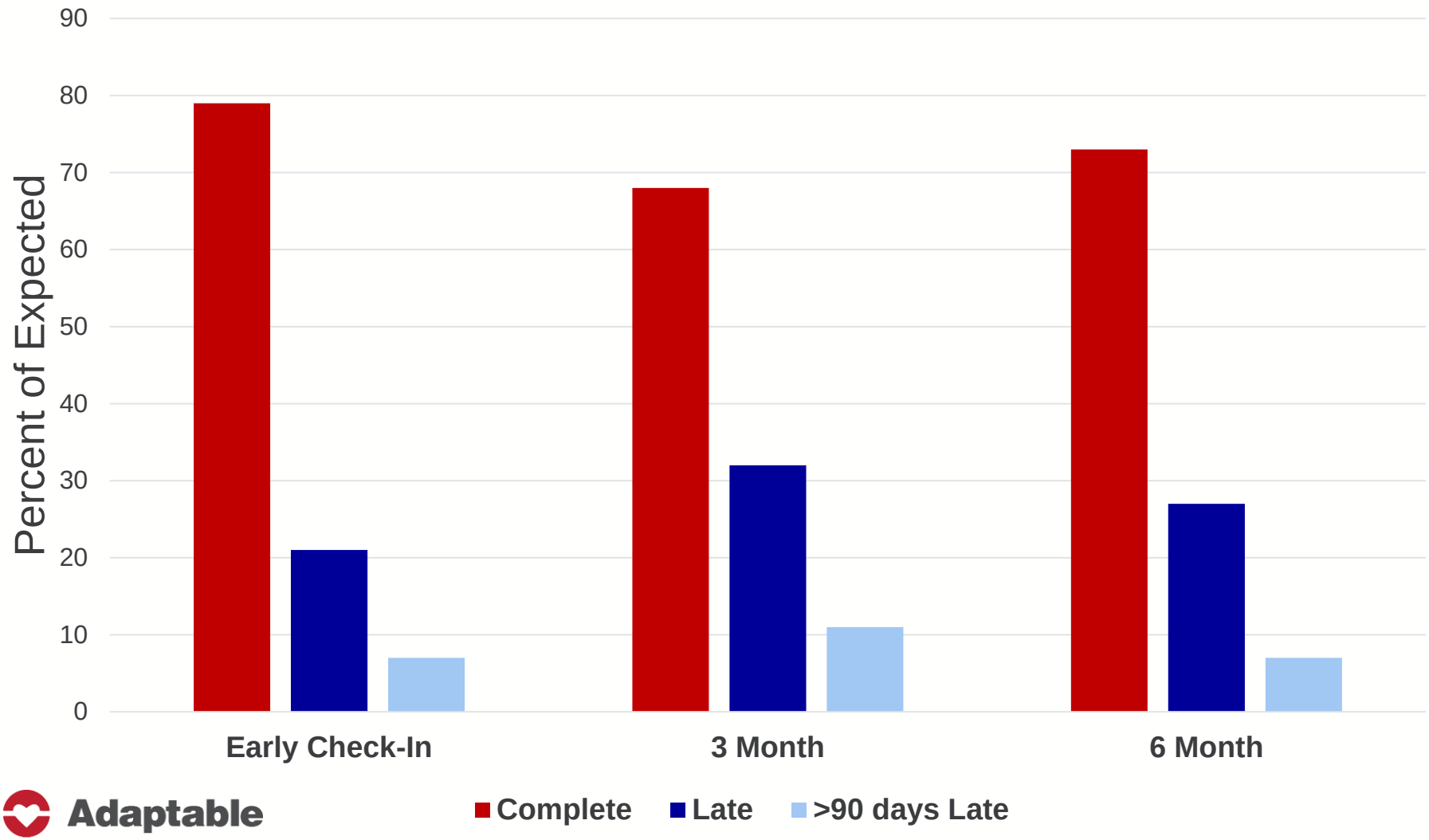


*Vanderbilt utilizes email as 1st contact

*Duke utilizes In-Clinic approach as 1st contact

Adaptable

Retention: Visit Status for Eligible Patients



Adaptable

Lessons Learned to Date

- Significant variation by CDRN/Recruitment Site
- Needed to expand Computable Phenotype to expand eligible patient pool
- Percent enrolled vs percent approached is very low
- Recruitment and retention needs to be multimodal
  - Email contact
  - Phone Call
  - Face-to-Face
- Recruitment needs to engage clinicians/patients/stakeholders
- Some patients need to be recruited with non-internet approaches
- Keep an eye on retention!

Summary

- PCORnet is a powerful network for pragmatic research
- Informatics approaches can help to identify, recruit, retain, and follow patients
- Informatics alone is insufficient to conduct pragmatic trials.

Acknowledgements

- Vanderbilt/ Meharry/VHAN
  - Paul Harrris MD
  - Trent Rosenbloom MD
  - Keri Wolfe MS, Megan Cook MS, Mellisa Basford MS
  - Sunil Kripalani MD
  - Christianne Roumie MD
  - Gordon Benard MD, Robert Dittus MD MPH
  - Dan Munoz MD
  - Bill Heerman MD, Ken Wallston PhD. David Schlundt PhD, David Crenshaw
  - Jonathan Schildcroudt PhD
  - Christina Eskew, Lesa Black PhD
  - Bobo Tanner MD
  - Wayne Jenkins MD
  - Marino Bruce PhD, Rowena Dolor MD
  - Yvonne Joosten MPH
  - Consuelo Wilkins MD
  - Duane Smoot MD
  - Sidd Pratha PhD
- PCORnet
  - Ben Nowell (AR-Power)
  - Jason Block MD (Partners)
- Duke
  - Ian Sanderson MD
  - Ebony Boulware MD
  - Adrian Hernandez MD
  - Matt Roe MD
  - Gene Oddone MD
  - Lauren Cohen
  - Meg Welch
  - Janice Curtis
  - ADAPTABLE TEAM
- UNC
  - Tim Carey MD MPH
  - Jacque Halladay MD
  - Darren DeWalt MD MPH
  - John Buse MD PhD CDE
- Health Sciences of South Carolina
  - Christy Turley MD
  - Katrina Friar Riley
  - Les Lenert MD (MUSC)
  - Jihad Obeid PhD
- Greenway Health
  - Sarah Pesko

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Questions