VANDERBILT UNIVERSITY

MEDICAL CENTER

Approaches to Queries for Cohort Identification

Paul Harris, PhD
Professor, Biomedical Informatics

Clinical Research FORUM
Analysis. Advocacy. Action.

Faculty/Staff

Community

Patients

VANDERBILT UNIVERSITY | StarBRITE

Recruitment

Participant recruitment can be one of the most difficult aspects of conducting human subjects research. Resources are available to help you achieve your study recruitment goals. Use the menu to the right to learn more about the resources available to your research team.

Resources

- **ResearchMatch**
  A national registry of potential research volunteers; to register as a researcher click here. To register as a volunteer click here.
- **VICTR Research Notifications Distribution List**
  Recruit study volunteers via the VICTR Research Notifications Distribution List that reaches over 18,500 Vanderbilt faculty and staff, and members of the Middle Tennessee community.
- **Subject Locator**
  Subject Locator assists researchers recruiting participants at Vanderbilt outpatient clinics by identifying patients with upcoming appointments that meet study inclusion/exclusion criteria. Learn more about how to use this this tool to reduce time spent pre-screening potential study participants here.
- **Vanderbilt Clinical Trials Registry**
  All actively recruiting studies in clinicaltrials.gov will be displayed on the Vanderbilt clinical trials website
- **AccrualNet**
  Strategies, Tools, & Resources to Support Accrual to Clinical Trials
- **MyResearch at Vanderbilt (MRAV)**
  A repository of over 17,000 Vanderbilt patients that have opted in to be contacted directly by e-mail to participate in research or to provide input on research ideas. Investigators may submit a request to contact these patients through MRAV with an IRB approved study description.
- The **Community Engagement Studio** is a guidance session for researchers interested in working in a community setting. Community members serve as experts and provide feedback to enhance the design **(including recruitment),** implementation, translation and dissemination of community engaged research. For more information contact Tiffany Israel, MSSW, at 615-875-5659 or tiffany.israel@vanderbilt.edu

Faculty/Staff

- **VICTR Research Notifications Distribution List**
  Recruit study volunteers via the VICTR Research Notifications Distribution List that reaches over 18,500 Vanderbilt faculty and staff, and members of the Middle Tennessee community.

LISTSERV

OR … OPT-OUT X

Subject: Healthy Controls Ages 16-30 Needed for Brain Imaging Study - Deleted Items

Message

Delete Reply Reply All Forward Meeting Attachment Move Junk Rules Read/Unread Categorize Follow Up

Subject: Healthy Controls Ages 16-30 Needed for Brain Imaging Study

research.notifications@vanderbilt.edu <research.notifications@vanderbilt.edu> sent by
owner-vumc-recruitment@list.vanderbilt.edu <owner-vumc-recruitment@list.vanderbilt.edu>
vumc-recruitment@list.vanderbilt.edu
Monday, October 23, 2017 at 4:02 PM
Show Details

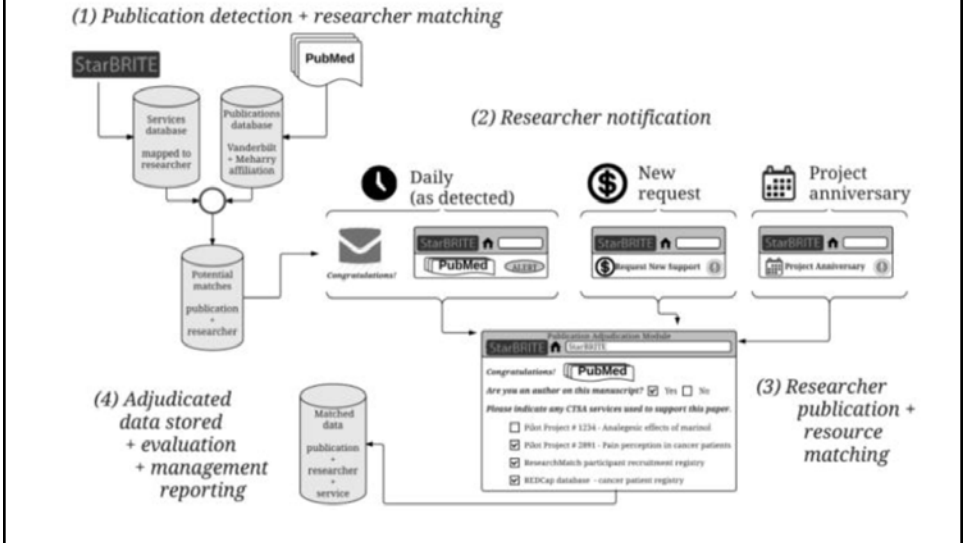
If you are a healthy adult with no history of psychological problems and no history of excessive substance or alcohol use, you may qualify as a normal control subject. This research study is looking at how genes and the brain work together to cause psychological disorders.

We Need:
Men and women ages 16-30 who are physically healthy.
Subjects may be asked to complete a screening survey, undergo a psychiatric interview, provide a blood and urine sample, and complete MRIs. Participants will be compensated for their time.

If you are interested or want more information about the study, please complete the screening survey at this link: https://redcap.vanderbilt.edu/surveys/?s=7J9SJncUPj. Once we have reviewed responses, you will be contacted regarding your eligibility.

If you are interested in more research opportunities in your community, consider joining ResearchMatch.org today! ResearchMatch.org is a collaborative project led by Vanderbilt Institute for Clinical & Translational Research to help 'match' you with additional research studies of interest to you.

You are a member of the Research Notifications distribution list. To unsubscribe, send an email to LISTSERV@LIST.VANDERBILT.EDU with the command UNSUBSCRIBE VUMC-RECRUITMENT in the body of your message.



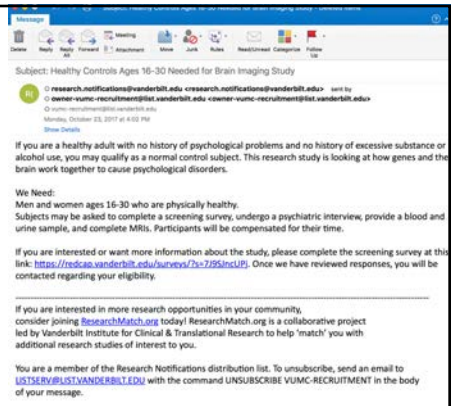
Acad Med. 2015 Aug;90(8):1043-50. doi: 10.1097/ACM.0000000000000732.

Tackling the "so what" problem in scientific research: a systems-based approach to resource and publication tracking.

Harris PA[1], Kirby J, Swafford JA, Edwards TL, Zhang M, Yarbrough TR, Lane LD, Helmer T, Bernard GR, Pulley JM.

ACADEMIC MEDICINE

LISTSERV



Subject: Healthy Controls Ages 16-30 Needed for Brain Imaging Study

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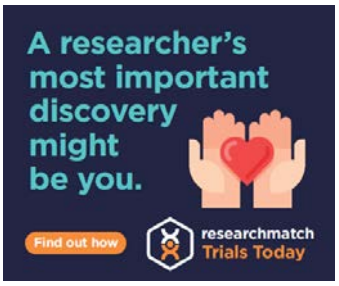
Number of Publications Matched to VICTR Resources by Year

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Recruitment Notifications	0	0	0	5	12	38	48	56	38	50	44

291 Publications



- **ResearchMatch**
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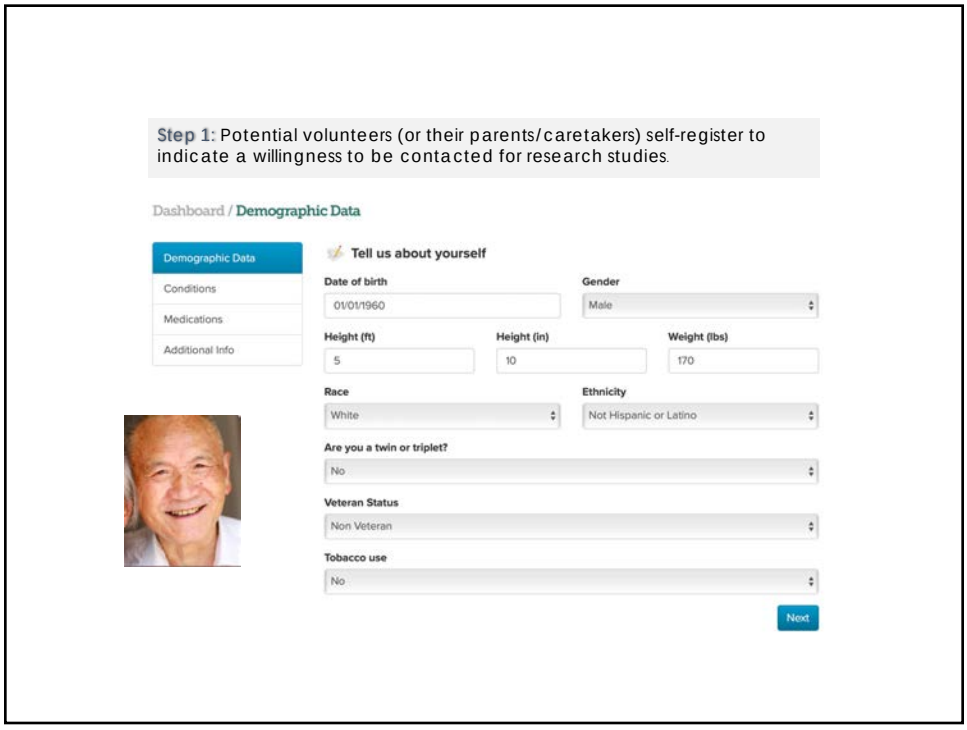
- **Vanderbilt Clinical Trials Registry**
  All actively recruiting studies in clinicaltrials.gov will be displayed on the Vanderbilt clinical trials website

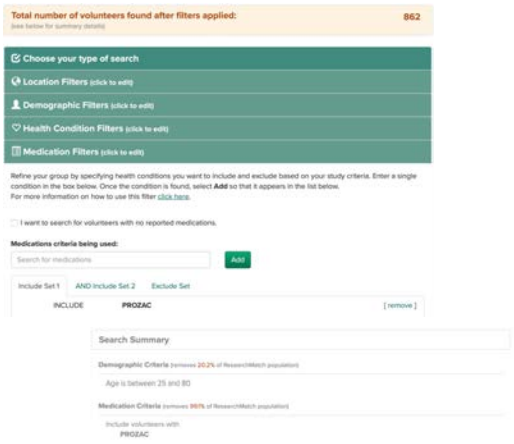

JOIN NOW
ABOUT
RESEARCHERS
NETWORK
TRIALS
RESULTS
CONTACT US
LOGIN
research match.org
Difficult diseases have met their match.
As of right now there are:
volunteers
researchers
studies
institutions
publications
122,591
5,315
573
142
255
more metrics
A Researcher's most important discovery might be you!
Medical discoveries are not possible without volunteers like you.
Health research changes people's lives every day. Researchers still need your help. Many studies end early because there are not enough volunteers. We help by matching you with research studies. Researchers need both healthy people and people with all types of conditions. Everyone can be the perfect research match!
Join Now
researchmatch.org


Step 1: Potential volunteers (or their parents/caretakers) self-register to indicate a willingness to be contacted for research studies.
Dashboard / Demographic Data
Demographic Data
Conditions
Medications
Additional Info
Tell us about yourself
Date of birth
01/01/1960
Gender
Male
Height (ft)
5
Height (in)
10
Weight (lbs)
170
Race
White
Ethnicity
Not Hispanic or Latino
Are you a twin or triplet?
No
Veteran Status
Non Veteran
Tobacco use
No
Next

Potential volunteers (or their parents/caretakers) self-register to indicate a willingness to be contacted for research studies.

Potential volunteers (or their parents/caretakers) self-register to indicate a willingness to be contacted for research studies.

Registered researchers search database for individuals based on study inclusion criteria and geographical location (Only De-Id Information)



Researchers send IRB approved recruitment message to 'matched' volunteers.

Volunteers make final choice to share identifiable information for direct contact.

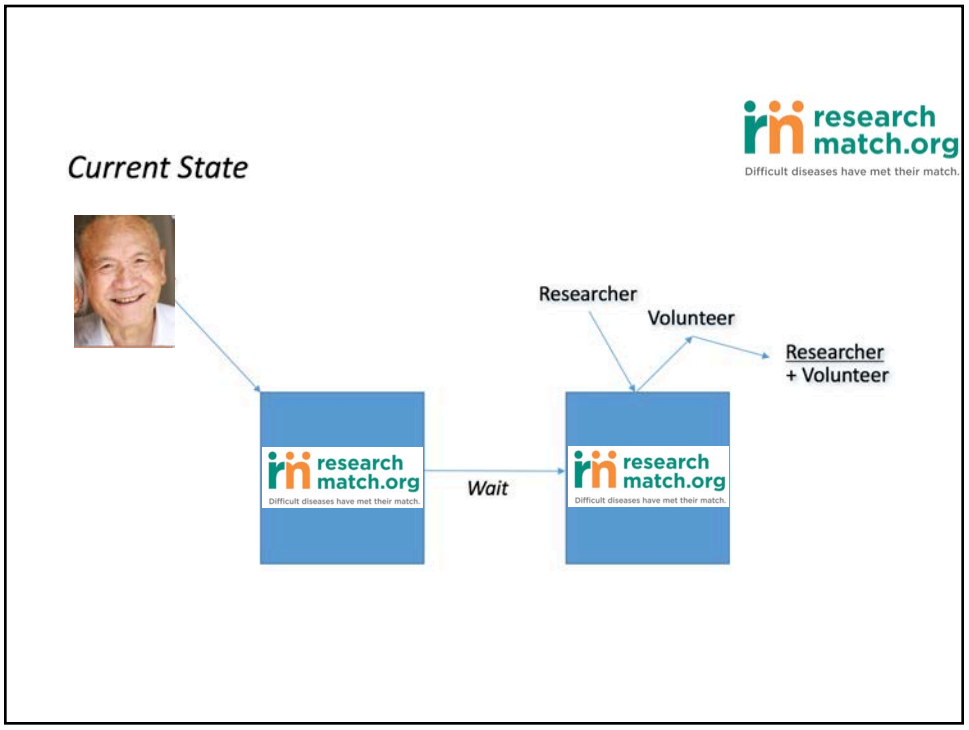
Researchers contact interested volunteers and follow normal study consent procedures.

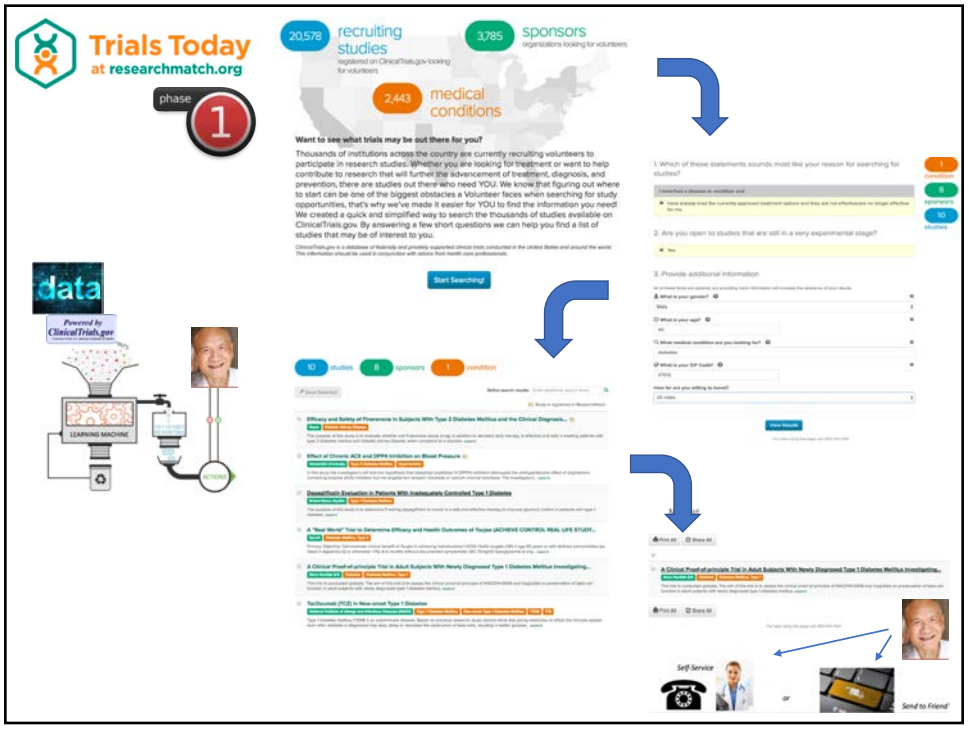

research match.org
Difficult diseases have met their match.

Number of Publications Matched to VICTR Resources by Year

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
ResearchMatch	0	0	0	4	3	16	15	25	19	30	40

152 Publications


Current State
research match.org
Difficult diseases have met their match.
Researcher
Volunteer
Researcher + Volunteer
research match.org
Difficult diseases have met their match.
Wait
research match.org
Difficult diseases have met their match.


Trials Today
at researchmatch.org
phase 1
data
Powered by ClinicalTrials.gov
LEARNING MACHINE
ACTIONS
20,578 recruiting studies
registered on ClinicalTrials.gov looking for volunteers
3,785 sponsors
organizations looking for volunteers
2,443 medical conditions
Want to see what trials may be out there for you?
Thousands of institutions across the country are currently recruiting volunteers to participate in research studies. Whether you are looking for treatment or want to help contribute to research that will further the advancement of treatment, diagnosis, and prevention, there are studies out there who need YOU. We know that figuring out where to start can be one of the biggest obstacles a Volunteer faces when searching for study opportunities, that's why we've made it easier for YOU to find the information you need! We created a quick and simplified way to search the thousands of studies available on ClinicalTrials.gov. By answering a few short questions we can help you find a list of studies that may be of interest to you.
Start Searching!
10 studies
8 sponsors
1 condition
1. Which of these statements sounds most like your reason for searching for studies?
2. Are you open to studies that are still in a very experimental stage?
3. Provide additional information
View Results
Self Service
or
Send to Friend

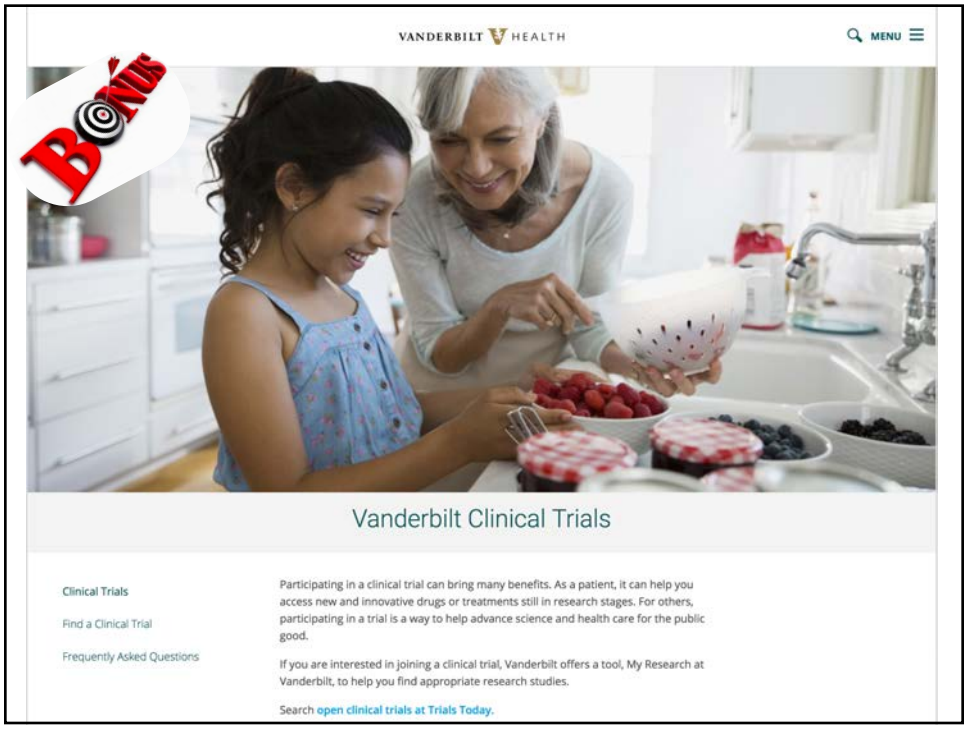
Trials Today
at researchmatch.org

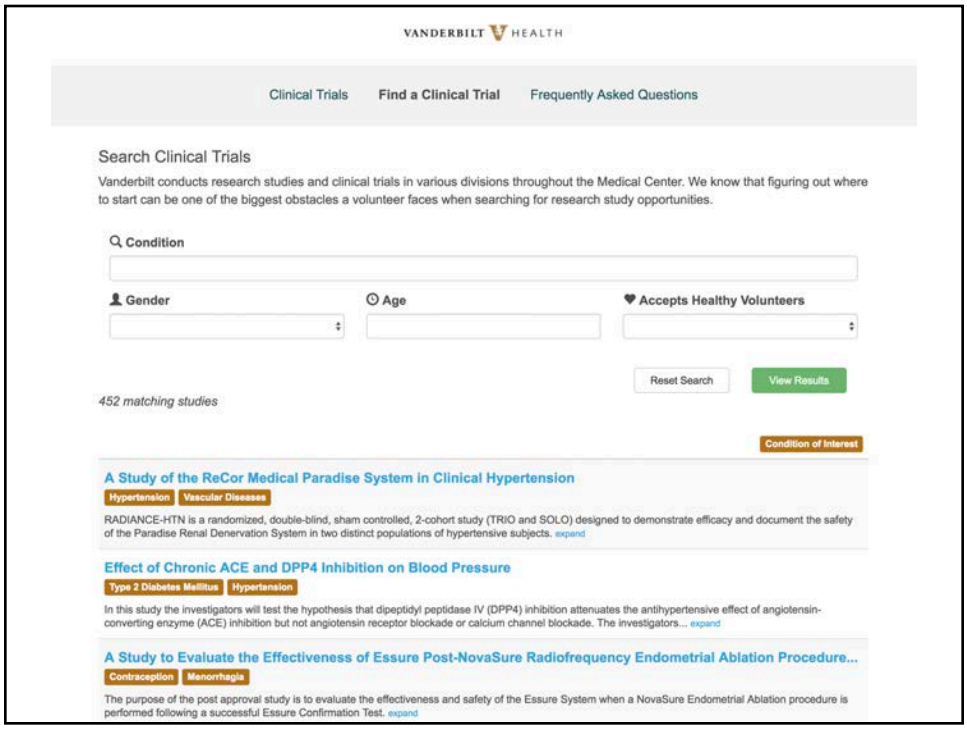
Number of Publications Matched to VICTR Resources by Year

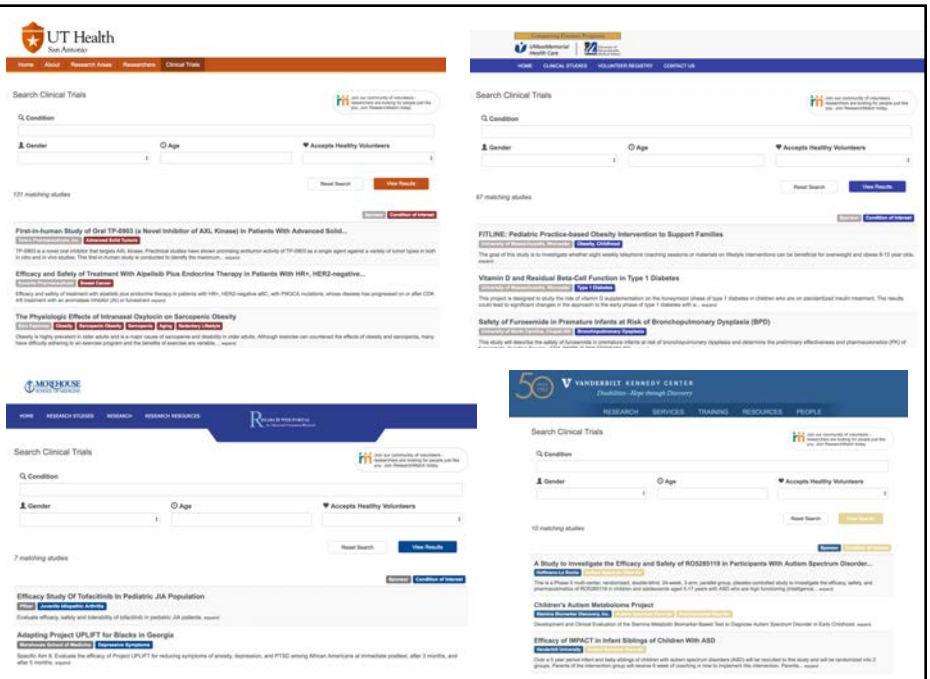
2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
										?

does it work?

It's Early … No Formal Evaluation Yet for Enrollment, But People are Clicking







Interested in Adopting/Collaborating? paul.harris@vanderbilt.edu

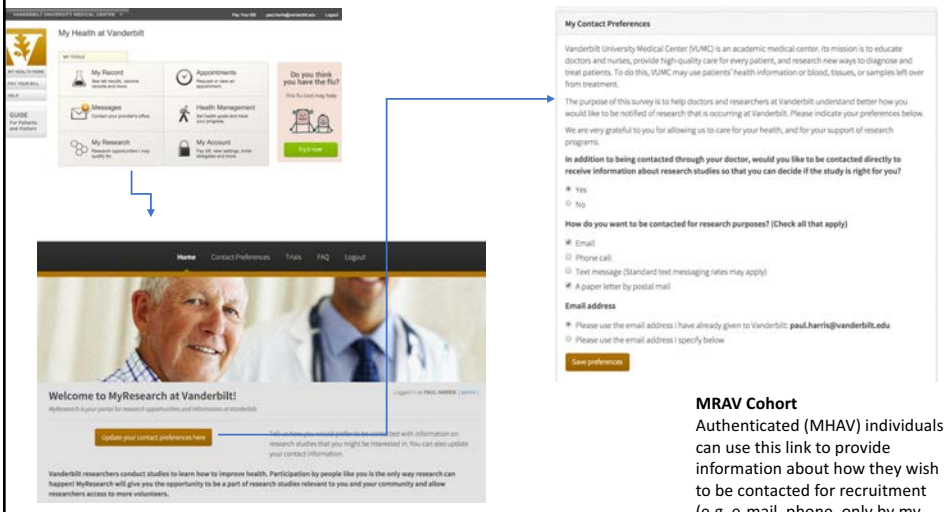
- **MyResearch at Vanderbilt (MRAV)**
  A repository of over 20,000 Vanderbilt patients that have opted in to be contacted directly by e-mail to participate in research or to provide input on research ideas. Investigators may submit a request to contact these patients through MRAV with an IRB approved study description.

- **Subject Locator**
  Subject Locator assists researchers recruiting participants at Vanderbilt outpatient clinics by identifying patients with upcoming appointments that meet study inclusion/exclusion criteria. Learn more about how to use this this tool to reduce time spent pre-screening potential study participants here.

MyResearch at Vanderbilt

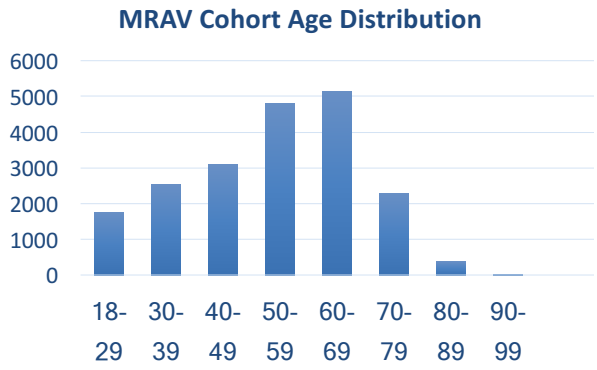
- An Informatics platform designed to continuously engage patients and offer opportunities to participate in research
- A cohort of ~ **20,000** Vanderbilt patients that have opted in to be contacted directly by e-mail to participate in research or to provide input on research ideas
- A convenient and efficient panel of patient representatives for which we have medical record data
- Uses: survey, clinical, interventional research and stakeholder engagement to guide research efforts

MyResearch at Vanderbilt

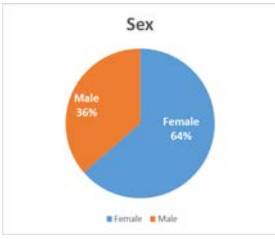


MRAV Cohort
Authenticated (MHAV) individuals can use this link to provide information about how they wish to be contacted for recruitment (e.g. e-mail, phone, only by my doctor, etc)

MyResearch at Vanderbilt



MRAV Cohort Top 5 Conditions
Hypertension NOS
Benign Hypertension
Diabetes Uncompl Type II
Hyperlipidemia NEC/NOS
Allergic Rhinitis NOS



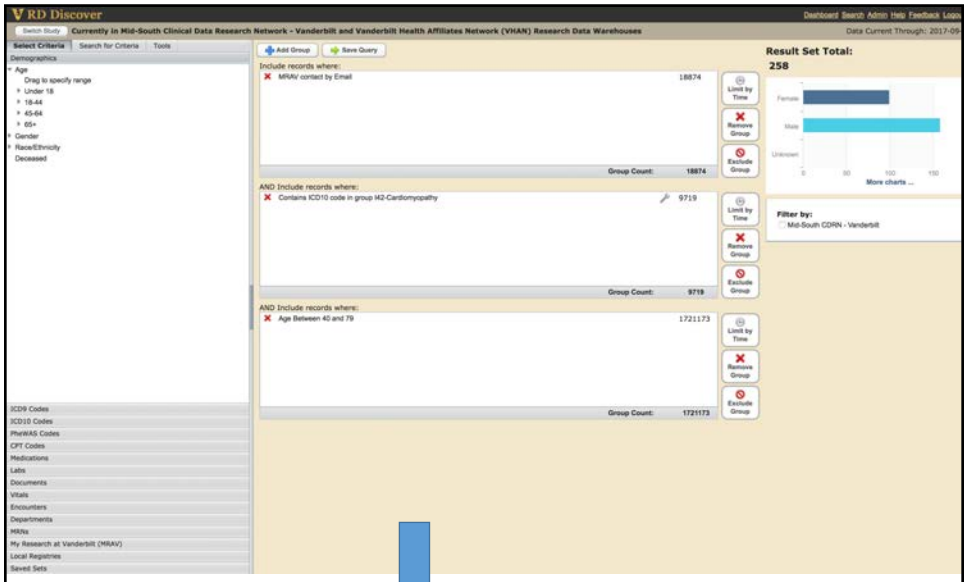
MyResearch at Vanderbilt

How to Recruit Patients From The MRAV Cohort

- Obtain IRB approval for use of MRAV recruitment tool and email contact language
- Submit a MyResearch Access Request
  - Reviewed for participant burden and availability of programmers
- Self-Service Identification through RD Discover Interface
- - or - submit a Research Derivative Request to identify eligible patients based on study criteria, if applicable (IDAS Core, $120 per programming hour)
- Once approved, Data Coordinating Center Core programmers send email notifications to participants including approved language ($82 per programming hour)

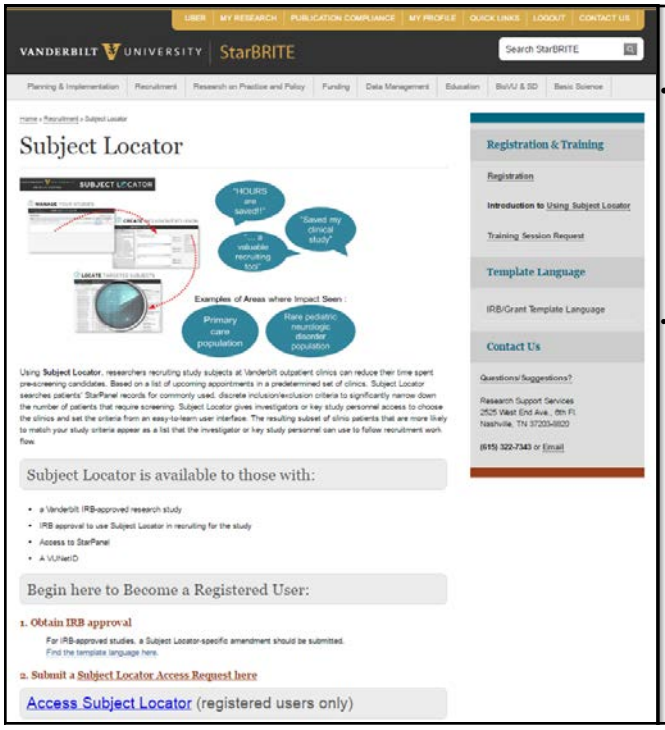
Expression of Interest / Pre-Screening Survey

REDCap
Research Electronic Data Capture

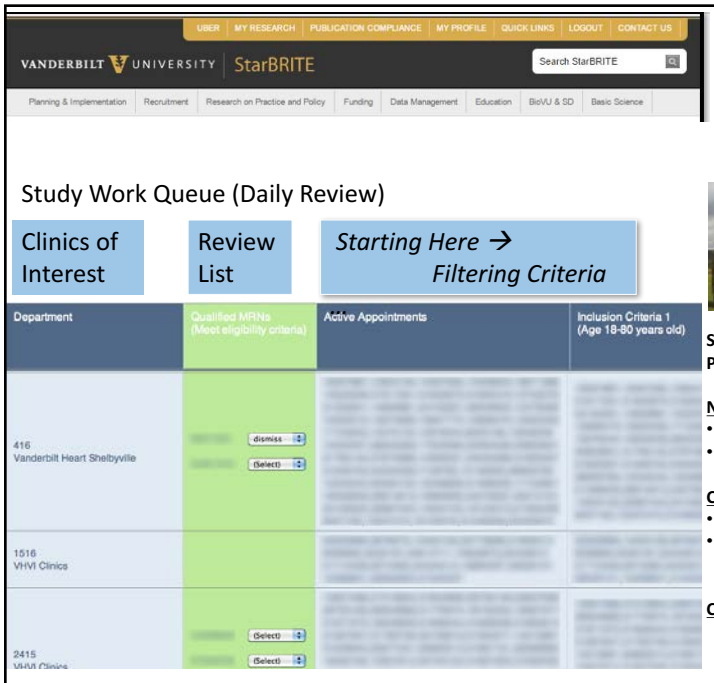


Expression of Interest / Pre-Screening Survey

REDCap
Research Electronic Data Capture



- Enables more efficient screening and recruiting of patients versus traditional methods of manually reviewing upcoming appointment lists and cross-referencing EMR
- Based on a list of upcoming appointments in a predetermined set of clinics, Subject Locator searches patient's EMR via the research data warehouse for commonly used, discrete inclusion/exclusion criteria to significantly narrow down the number of patients that require screening
  - Criteria includes IC9/10 and CPT codes, demographics, vitals, keywords, medications



Snapshot – Pilot Studies

Nephrology
- Examined: 2598
- Candidates: 96

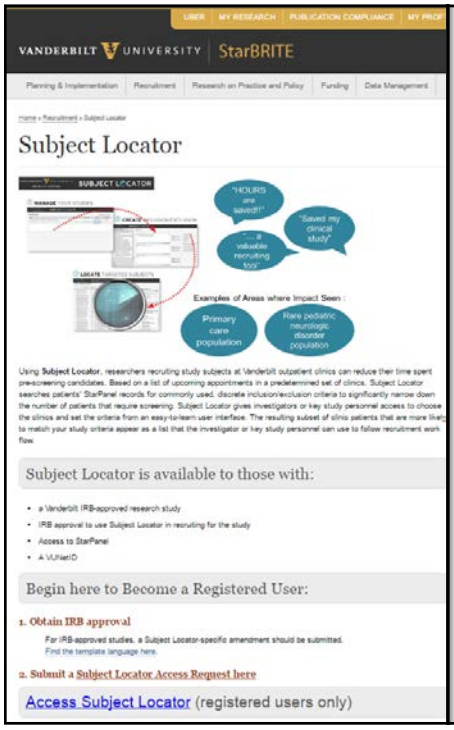
(reduction - 96%)

Cleft Palate
- Examined: 2490
- Candidates: 27

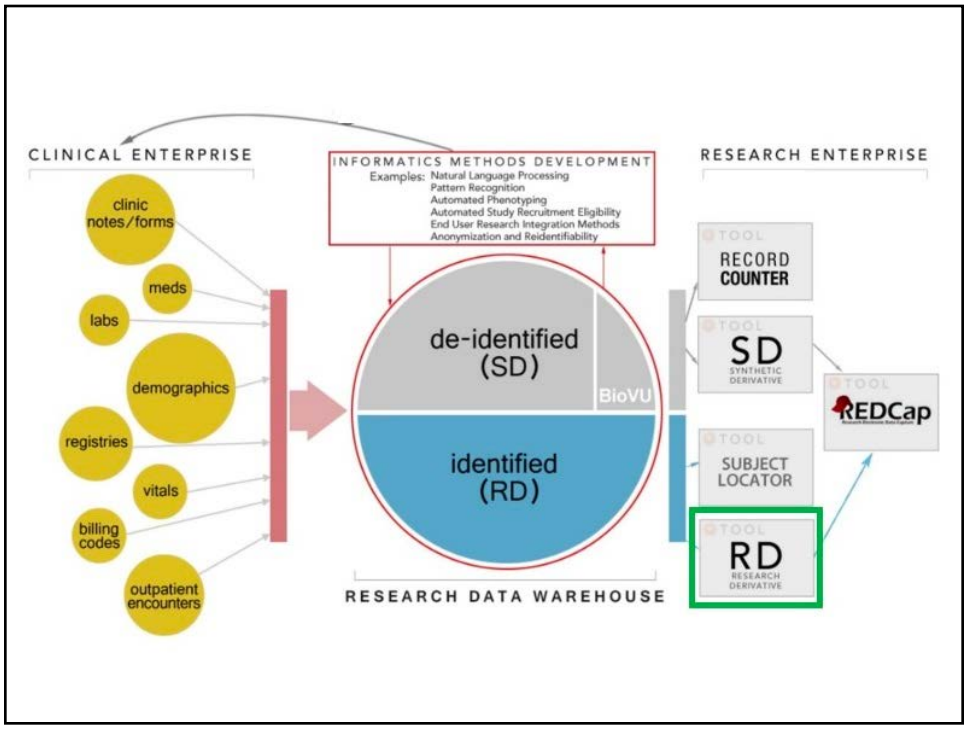
(reduction - 99%)

Cardiology (2 studies)

(reduction - 95%)



Data types available in the RD Discover:	Set Creation	Data Export
Demographics (age, sex, race, deceased status)	X	X
ICD Codes	X	X
CPT Codes	X	X
PheWAS Codes	X	X
Medications	X	
Lab Values	X	X
Documents (search for keyword text strings)	X	
Vital Signs (BMI, BP, weight, height, pulse, RR)	X	X
Encounters (inpatient, outpatient, ED)	X	
Departments (inpatient, outpatient, provider name)	X	
Tumor Registry	X	X
MRNs	X	X
My Research at Vanderbilt (MRAV) cohort	X	
Contact Information		X



BioVU

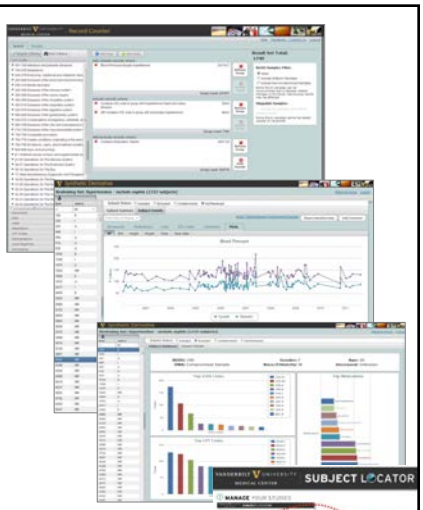
- Links DNA extracted from discarded blood samples to de-identified EMR
- ~177k DNA samples, over 20k pediatric
- 74 BioVU projects approved to date

Synthetic Derivative

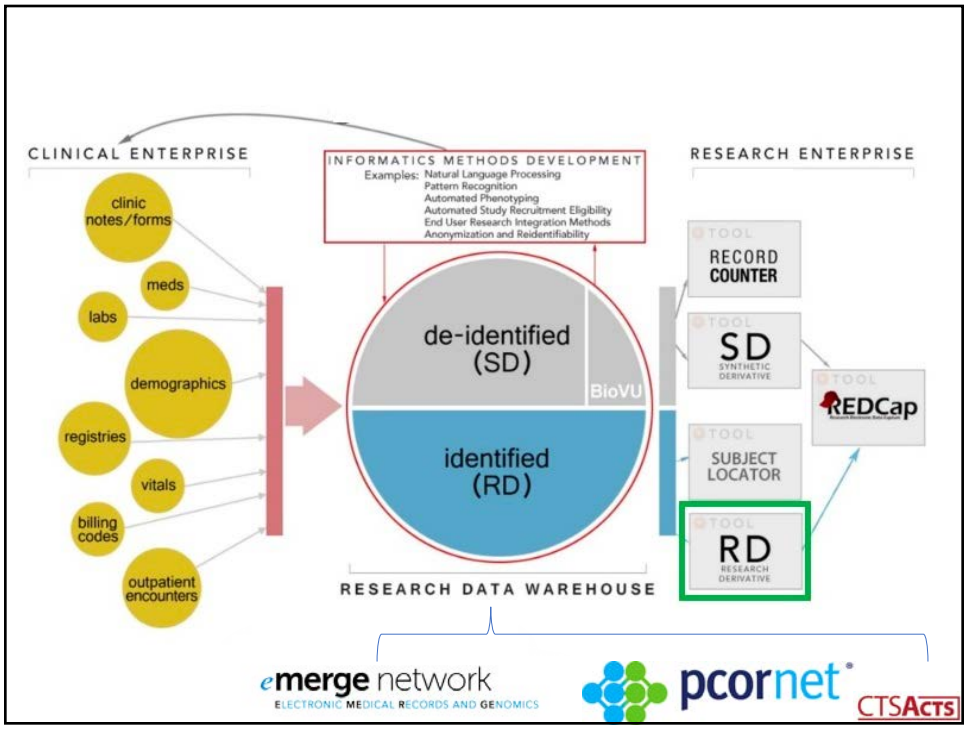
- Research tool to enable studies with de-identified clinical data
- Contains 2.5 million records; highly detailed longitudinal clinical data for ~1 million

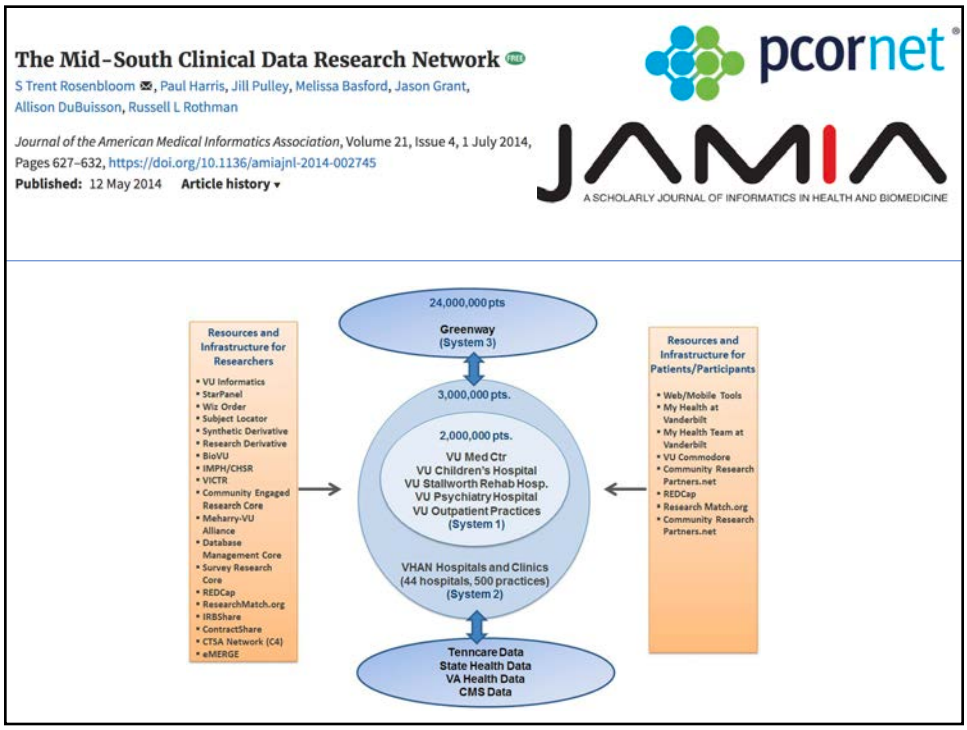
Research Derivative

- Identified clinical data warehouse
- Tools (e.g. Subject Locator)
- Services (Fee for Service)
- New REDCap extraction toolkit



Tool Development Driven by Experience and Use Cases


CLINICAL ENTERPRISE
INFORMATICS METHODS DEVELOPMENT
Examples: Natural Language Processing
Pattern Recognition
Automated Phenotyping
Automated Study Recruitment Eligibility
End User Research Integration Methods
Anonymization and Reidentifiability
RESEARCH ENTERPRISE
clinic notes/forms
meds
labs
demographics
registries
vitals
billing codes
outpatient encounters
de-identified (SD)
BioVU
identified (RD)
RESEARCH DATA WAREHOUSE
TOOL RECORD COUNTER
TOOL SD SYNTHETIC DERIVATIVE
TOOL REDCap
TOOL SUBJECT LOCATOR
TOOL RD RESEARCH DERIVATIVE
emerge network
ELECTRONIC MEDICAL RECORDS AND GENOMICS
pcornet
CTSActs


The Mid-South Clinical Data Research Network
S Trent Rosenbloom, Paul Harris, Jill Pulley, Melissa Basford, Jason Grant, Allison DuBuisson, Russell L Rothman
Journal of the American Medical Informatics Association, Volume 21, Issue 4, 1 July 2014, Pages 627–632, https://doi.org/10.1136/amiajnl-2014-002745
Published: 12 May 2014 Article history
pcornet
JAMIA
A SCHOLARLY JOURNAL OF INFORMATICS IN HEALTH AND BIOMEDICINE
Resources and Infrastructure for Researchers
• VU Informatics
• StarPanel
• Wiz Order
• Subject Locator
• Synthetic Derivative
• Research Derivative
• BioVU
• IMPH/CHSR
• VICTR
• Community Engaged Research Core
• Meharry-VU Alliance
• Database Management Core
• Survey Research Core
• REDCap
• ResearchMatch.org
• IRBShare
• ContractShare
• CTSA Network (C4)
• eMERGE
24,000,000 pts
Greenway (System 3)
3,000,000 pts.
2,000,000 pts.
VU Med Ctr
VU Children's Hospital
VU Stallworth Rehab Hosp.
VU Psychiatry Hospital
VU Outpatient Practices
(System 1)
VHAN Hospitals and Clinics
(44 hospitals, 500 practices)
(System 2)
Tenncare Data
State Health Data
VA Health Data
CMS Data
Resources and Infrastructure for Patients/Participants
• Web/Mobile Tools
• My Health at Vanderbilt
• My Health Team at Vanderbilt
• VU Commodore
• Community Research Partners.net
• REDCap
• Research Match.org
• Community Research Partners.net

Desiderata for computable representations of electronic health records-driven phenotype algorithms

Huan Mo, William K Thompson, Luke V Rasmussen, Jennifer A Pacheco, Guoqian Jiang, Richard Kiefer, Qian Zhu, Jie Xu, Enid Montague, David S Carrell Todd Lingren, Frank D Mentch, Yizhao Ni, Firas H Wehbe, Peggy L Peissig, Gerard Tromp, Eric B Larson, Christopher G Chute, Jyotishman Pathak, Joshua C Denny, Peter Speltz, Abel N Kho, Gail P Jarvik, Cosmin A Bejan, Marc S Williams, Kenneth Borthwick, Terrie E Kitchner, Dan M Roden, Paul A Harris

Journal of the American Medical Informatics Association, Volume 22, Issue 6, 1 November 2015, Pages 1220–1230, https://doi.org/10.1093/jamia/ocv112

eMERGE network
ELECTRONIC MEDICAL RECORDS AND GENOMICS

JAMIA
A SCHOLARLY JOURNAL OF INFORMATICS IN HEALTH AND BIOMEDICINE

•Recommendations for clinical data representation to support phenotyping
- 1. Structure clinical data into queryable forms.
- 2. Recommend use of a common data model, but also support customization for the variability and availability of EHR data among sites.

•Recommendations for phenotype representation models
- 3. Support both human-readable and computable representations.
- 4. Implement set operations and relational algebra.
- 5. Represent phenotype criteria with structured rules.
- 6. Support defining temporal relations between events.
- 7. Use standardized terminologies, ontologies, and facilitate reuse of value sets.
- 8. Define representations for text searching and natural language processing.
- 9. Provide interfaces for external software algorithms.
- 10. Maintain backward compatibility.

r!c RECRUITMENT INNOVATION CENTER

r!c PARTNERS

Trial Innovation Network Hub Liaison Teams

The Ohio State University Wexner Medical Center

Columbia University Medical Center

The Rockefeller University
Science for the benefit of humanity

Regenstrief Institute
Better Care. Better Health.

Vanderbilt University Medical Center

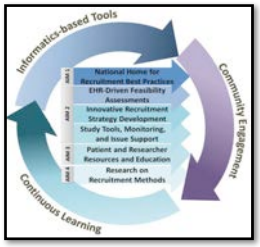
University of Utah Health Sciences

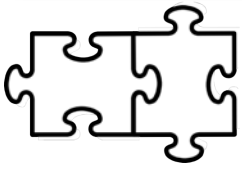
r!c

Vision and purpose

Our goal is to positively impact human health by **improving participant enrollment and retention in multi-center clinical trials**.

Achieving this goal will require sophisticated **informatics-based recruitment tools** and **novel engagement approaches** to accelerate recruitment and retention.





r!c

Key Principles

- **Respecting CTSA autonomy and diversity**
- A focus on minority and underserved populations
- **Making the most of electronic health records**
- Preserving a disease neutral approach
- Focus on cost efficiency
- Respecting and returning value to participants
- Build on best practice (avoid reinventing the wheel)
- Evidence based…. What works? (test bed)
- Finite resources – scalability / tools
- Home for recruitment experts (across + beyond CTSA)

r!c

EHR-Based Site Feasibility

BE OPPORTUNISTIC

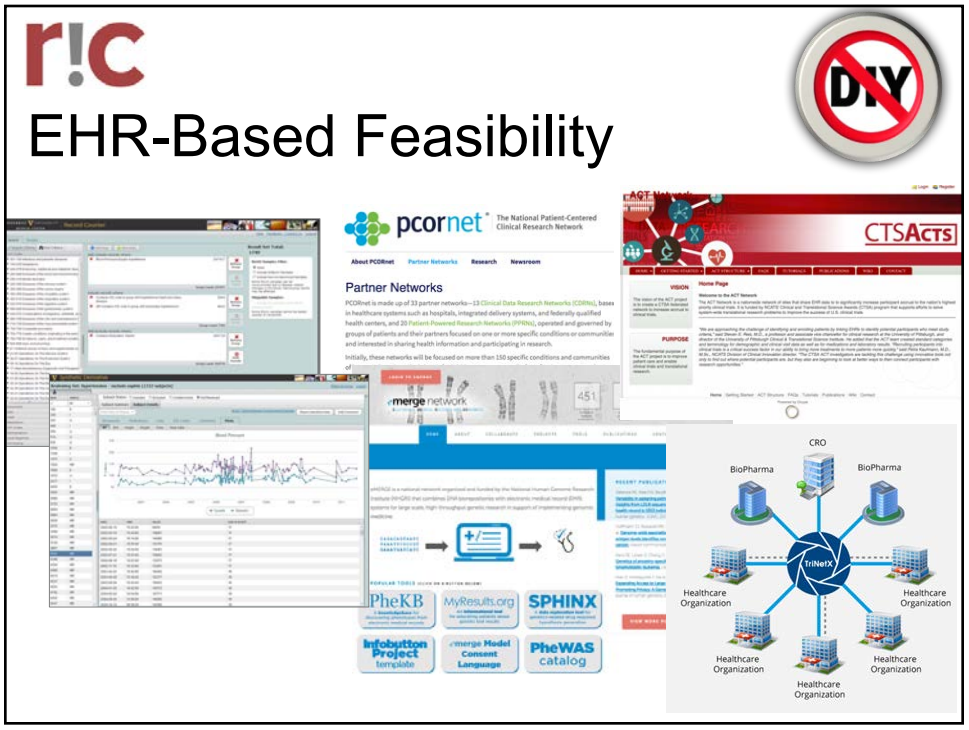
"If I have seen further than others, it is by standing upon the shoulders of giants."

– Sir Isaac Newton

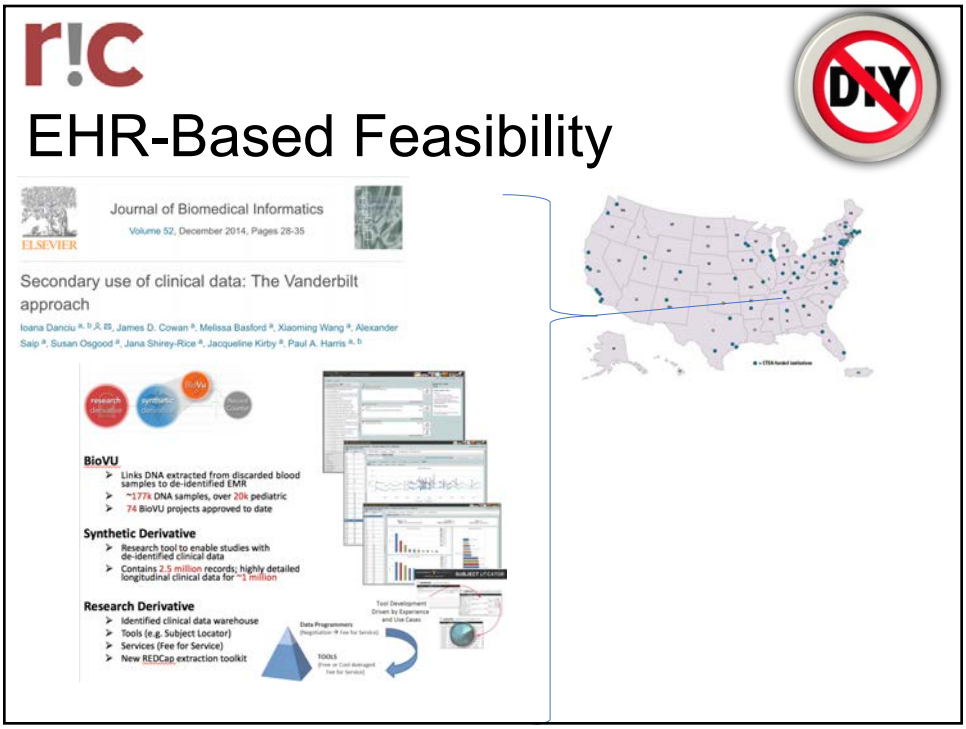
Do what you can, with what you have, where you are.

Theodore Roosevelt

EHR-Based Feasibility



EHR-Based Feasibility



Clinical and Translational Science Award (U54)

Informatics

Per the IOM report, "The challenge for the next phase of the CTSA Program will be to establish a more integrated and collaborative national network t… development of new diagnostics, therapeutics, and preventive interventions while driving innovation in clinical and translational research methods, pro… and leveraging the ever-expanding capabilities of health informatics tools and other research technologies".

Biomedical informatics is a critical CTSA focus for enabling and advancing translational research, which is increasingly data intensive, and requires collabora… communities, including healthcare, research, and public health. Additionally, the increasing amounts and types of data (e.g., genetic, imaging, clinical, economic, environmental, behavioral, patient reported) need to be integrated to generate knowledge. Cooperation and coordination among the data stewards in various organizations and institutions on policy issues, and among the managers of those data systems on technical issues are critical. This section should describe how the applicant will facilitate exchange of data among various sources required by translational researchers. Organizational, policy, and technical issues should be addressed. This section should explain how electronic or other medical records interface with clinical research data systems.

CTSA hubs should offer researchers a user-friendly data management system along with training on its use and some basic support. CTSA applicants should encourage compatibility of their research systems with broadly accepted content and technical standards including those adopted by the Department of Health and Human Services for use in U.S. health care and public health operations. In addition, as NIH Institutes and Centers adopt common data elements in their domain areas, CTSA hubs should ensure their research tools are compatible (see http://www.nlm.nih.gov/cde/Home for more information).

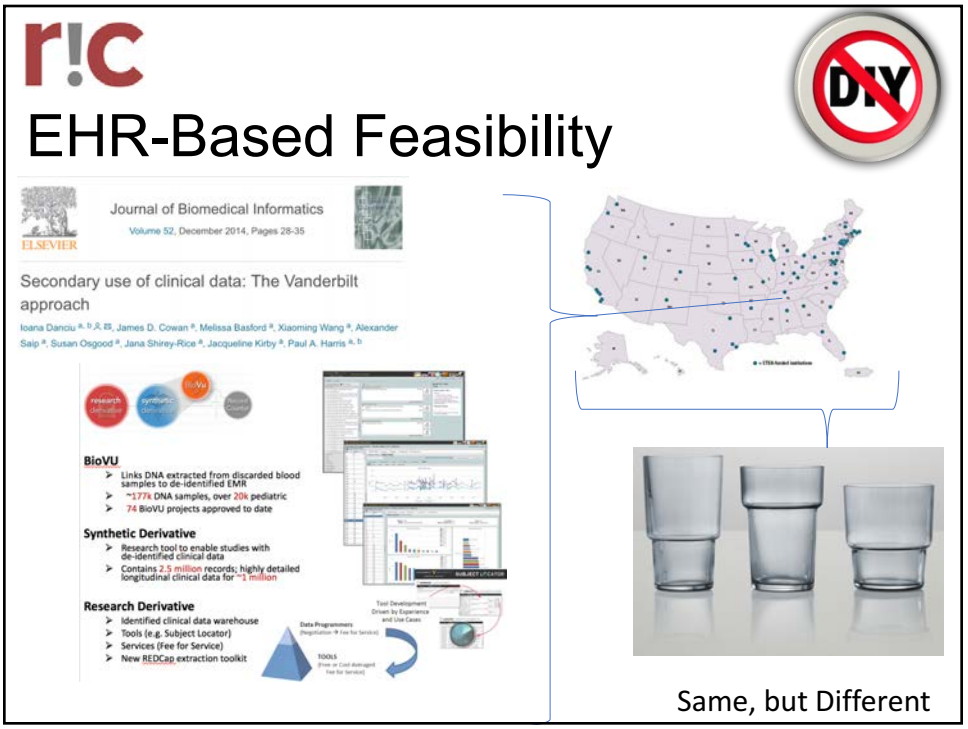
Maintaining the security of study data, particularly in studies involving human subjects, is critical. Many clinical and translational researchers manage such data in systems, processes, and formats that lack appropriate security. Academic institutions vary in the availability of low cost and user friendly infrastructure to assist investigators in ensuring the security of their data or in their requirements for its use by faculty, staff, and students. Applicants must describe their plan for ensuring the security of research data on all studies involving human subjects at all participating institutions. This plan should address policy, workflow, technical, and enforcement issues. The plan should outline challenges and possible alternative approaches for surmounting them.

CTSA hubs should work towards a flexible, sustainable digital enterprise where digital assets are interoperable so that, for example, data from the electronic health record (EHR) can be used for research purposes. This will require informatics solutions that are embedded in HIPAA regulations and other measures to safeguard patient privacy and autonomy. CTSA hubs should support a research-friendly integrated IT environment where information on applicable research opportunities is presented to clinicians and patients via EHR at the time of the clinical encounter. Other useful services might include noting a patient's participation in a research study in the clinical EHR for the benefit of the treating clinician, and efficient routing of laboratory results. Applicants should describe any solutions they currently have locally to integrate health care and research data, as well as plans for the future. Applicants should indicate if they are currently participating in initiatives that make use of EHR data for research or surveillance (such as for example Mini-Sentinel, PopMedNet/PCORNet, i2b2, or SHRINE), and how they integrate participation with these initiatives into their local digital enterprise and network activities.

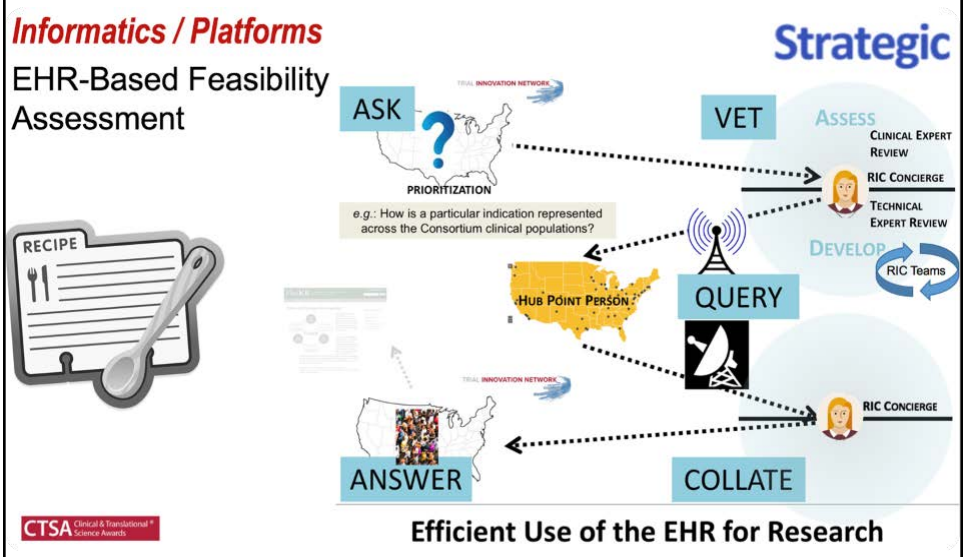
To accelerate translation, CTSA hubs should work towards data sharing and enabling data access, integration and processing. Applicants should indicate whether they have initiatives at their hub that support data sharing, how they promote broad use of data, and how they encourage investigators to submit data to repositories (see for example NIH Data Sharing Repositories). In this context, applications should also describe how they train researchers to prepare for downstream data sharing, such as by providing training and sample language for research-friendly consent forms that support broad data use (not limited to time, place or purpose), and that avoid complex nested formats to the extent possible. This is based on the observation that patients consenting to research participation are often information altruists who welcome the secondary use of research data so long as appropriate measures have been taken to protect their privacy. Applicants should also describe how they might collaborate with other CTSA hubs on using common data standards in multi-site projects.

NCATS attaches importance to assessments of informatics performance and goal setting across the entire CTSA community. Therefore informatics leadership from each CTSA is expected to participate in national CTSA network informatics activities, and the application should indicate an informatics point person that can serve as liaison to the network. The CTSA hubs are encouraged to share their informatics tools, and to adopt and utilize tools developed by others to avoid duplication and redundancy. The CTSA hub must be committed to working toward adoption and implementation of standards and practices endorsed by the CTSA program.

EHR-Based Feasibility



EHR-Based Feasibility



EHR-based Cohort Assessment

Non-federated strategic approach to cohort identification by utilizing established network resources to inform various components of the clinical trial process.

Key features:

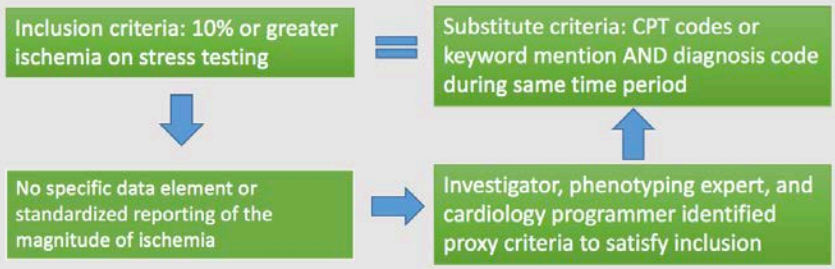
3 stages facilitated by RIC Concierge

Tiered algorithms

Custom phenotypes vetted on multiple platforms

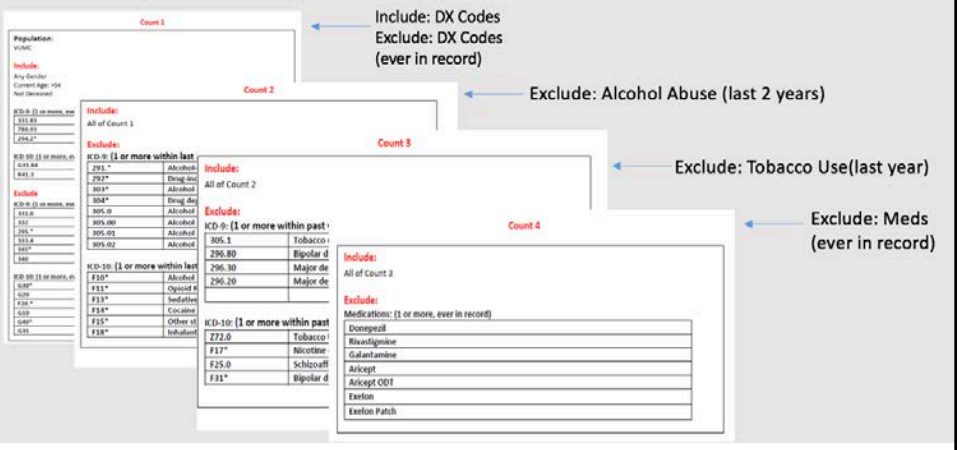
EHR-based Cohort Assessment Stage 1: Defining the ask

One-on-one discussions with study team to define need for cohort identification, assess inclusion/exclusion criteria, identify proxy data points to satisfy unique study criterion

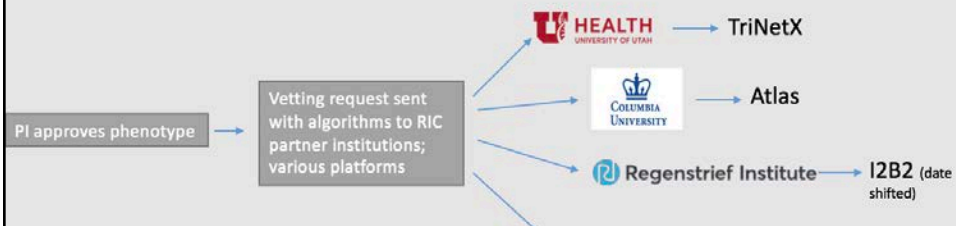


EHR-based Cohort Assessment Stage 1: Defining the ask

Creating tiered phenotypes show attrition rates



EHR-based Cohort Assessment Stage 2: Vetting



During vetting, institutions can ask questions, make suggestions, and determine limitations. Changes in algorithm are communicated to PI for approval before re-vetting

EHR-based Cohort Assessment Stage 3: Network query

-PI can choose sites to query.
-Sites can 'opt-out' for any reason.
-Initial feedback is positive; lessons learned

YOU ARE HERE

Framing The EHR Request to CTSA Hub

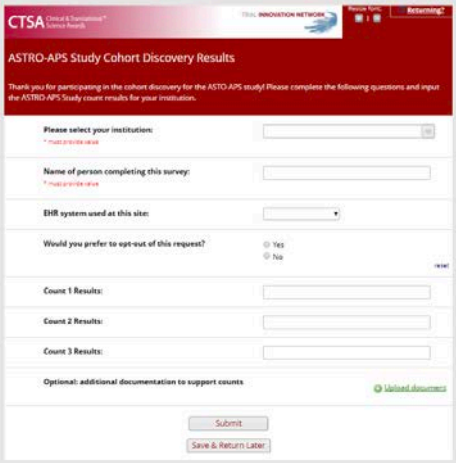
Request to be made to Hub Liaison POC from TIC (or RIC)

- Protocol Summary + Investigator Team Information
- Project Status (Recruiting/Funded – or - Prospective)
- Expected Number of Sites
- Timeline for Information + Expression of Interest Request
- General Contact information for questions
- Connection information for a 1-time webinar (recorded)
- Instructions for EHR-based data interrogation
  - Connect with your local informatics core
  - Deliver query algorithm (algorithm will most likely be multi-tiered to accommodate 'data diversity' at CTSA hubs)
  - Post-Query Aggregate Data Collection - REDCap Survey
  - Specific point of contact (from RIC) questions
- Instructions for Expression of Interest
  - Contact PI + Contact Information

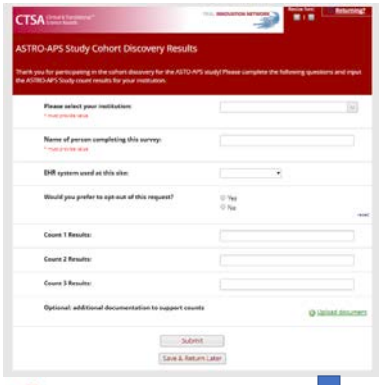
EHR-based Cohort Assessment Stage 3: Network query

Submitting Results:

- Simple submission process
- Ability to save and return if needed
- Ability to upload supporting documentation
- Option to opt-out
- User-friendly well-known REDCap platform



EHR-based Cohort Assessment Stage 3: Network query



REDCap
Research Electronic Data Capture

REDCap
Research Electronic Data Capture
PLUG IN

Cohort Discovery Survey Response Tracking Report

Select a project: RIC: Cohort Discovery Service (MIND)

Responses: 70% (21 of 30)
Average Response Time: 6 days

Site	Response Time (in days)
Albert Einstein College of Medicine (partnering with Montefiore Medical Center)	No Response
Childrens National Medical Center	No Response
Dartmouth College	No Response
Emory University (partnering with Morehouse School of Medicine and Georgia Institute of Technology)	6
Harvard University	No Response
Indiana University School of Medicine	1
Mayo Clinic	5
Medical College of Wisconsin	No Response
Medical University of South Carolina	8
Penn State Milton S. Hershey Medical Center	1
State University of New York at Buffalo	5
The Ohio State University	1
The Rockefeller University	No Response
The Scripps Research Institute	19
Tufts University	7
University of Arkansas for Medical Sciences	8
University of California, San Diego	No Response
University of Chicago	12

EHR-based Cohort Assessment Stage 3: Network query

Example results; detailed site information included n separate tabs, including demography, race, and ethnic breakdown (if provided by site).

CTSA Institution	Count 1 Results:	Count 2 Results:	Count 3 Results:	Count 4 Results:
[redacted]	9731	9505	9106	7302
	8432	8021	7739	6742
	1066	1066	1066	1059
	15779	15295	14931	12261
	4563	4432	4290	3546
	11594	11013	10945	7665
	804	789	767	605
	1200	1130	970	710
	4135 total	3953 total	388 total	306 total
	20678	19838	18998	16922
	35263	34001	32919	29584
	13661	12918	12246	10689
	816	787	763	576
	14937	14675	14439	11042
	6680	6365	6080	4913
	15693	14899	11607	N/A
	30653	27835	23708	N/A
	3607	2520	1864	1858
	4310	4147	3879	3233
	8162	8001	7792	5997

EHR-based Cohort Assessment Results of Network Queries

STUDY 1-9/14

4 counts requested at 29 sites
Response rate: 72%
Average Response: 6 days

Study 1: actively recruiting study needing additional sites

STUDY 2-9/15

3 counts requested at 60 sites
Response rate: 50%
Average Response: 8 days

Study 2: newly funded study for site selection

STUDY 3-10/20

3 counts requested at 60 sites
Response rate: 20%
Average Response: 8 days

Study 3: pilot study selecting additional sites

EHR-based Cohort Assessment

CASE STUDY

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Find Studies | About Studies | Submit Studies | Resources | About Site

Home > Study Record Detail

Memory Improvement Through Nicotine Dosing (MIND) Study (MIND)

This study is currently recruiting participants.
See Contacts and Locations

Verified August 2017 by Paul Aisen, University of Southern California

Sponsor:
University of Southern California

Collaborators:
National Institute on Aging (NIA)
Vanderbilt University
Alzheimer's Therapeutic Research Institute

Information provided by (Responsible Party):
Paul Aisen, University of Southern California

ClinicalTrials.gov Identifier:
NCT02720445

First received: March 22, 2016
Last updated: August 10, 2017
Last verified: August 2017
History of Changes

Efficient Use of the EHR for Research

Non-Fed Fed

TriNetX

EHR-based Cohort Assessment

CASE STUDY

MIND - Cohort Identification-Feasibility -TriNetX Results

Principal Investigator: Paul Newhouse
Vanderbilt University
EHR Cohort Discovery-Phase 1

	TriNetX ALL	TriNetX-CTSA
Count 1	238770	172,500
Count 2	233,168	168,710
Count 3	214,630	157,650
Count 4	182,630	129,660

238,770 COUNT 1 RESULTS – PATIENTS PER HCO

233,310 COUNT 2 RESULTS – PATIENTS PER HCO

214,630 COUNT 3 RESULTS – PATIENTS PER HCO

181,630 COUNT 4 RESULTS – PATIENTS PER HCO

Cohort By Site

= CTSA hub

TriNetX Summit 2017

EHR-based Cohort Assessment

Related Results

Federated

Counts	TriNetX Counts	Difference between counts	TriNetX (CTSA Sites)	Difference between counts
Count 1	237,770		172,500	
Count 2	233,310	2.28%	168,710	2.19%
Count 3	214,630	8.00%	157,650	6.56%
Count 4	181,630	15.0%	129,660	17.75%

Non-Federated

Vanderbilt	Difference between counts	RIC	Difference between counts
9,731		39,571	
9,505	2.32%	38,319	3.16%
9,106	4.20%	37,132	3.10
7,302	19.81%	7,302	16.76%

The change in the counts is virtually the same between Federated and Non-Federated

TriNetX Summit 2017

EHR-based Cohort Assessment Lessons Learned

Non-Federated approach works

Feedback during RIC vetting and Network Query Request stages have provided valuable information about data limitations and site uniqueness.

Examples:

Epic slicer/dicer tool allows one code occurrence in record, not 2 or more- not a limitation but supports inconsistencies

6 Hub sites need LOINC codes for lab criteria

+ Need Federated to do sophisticated sensitivity analysis of inclusion/exclusion rules

EHR-based Cohort Assessment Uses

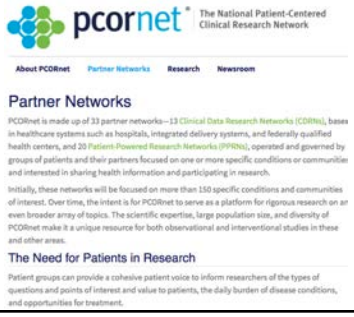
	Site Selection	LOI/Grant	Budget Planning	Study/Protocol Design	Rescue/low enrollment	Recruitment Planning/Materials
Study 1	■					■
Study 2	■					
Study 3	■					
Study 4		■	■	■		■
Study 5			■			
Study 6			■			
Study 7					■	
Study 8		■				
Study 9		■				
Study 10				■		
Study 11		■	■	■		
Study 12	■		■			
Study 13		■	■	■		

We're working on joining …

We're working on leveraging …

We're working on joining …

We're working on leveraging …



Effoe *et al. Trials* (2016) 17:496
DOI 10.1186/s13063-016-1631-7

Trials

RESEARCH Open Access

The use of electronic medical records for recruitment in clinical trials: findings from the Lifestyle Intervention for Treatment of Diabetes trial

Valery S. Effoe[1,2*], Jeffrey A. Katula[3], Julienne K Kirk[4], Carolyn F Pedley[5], Linda Y. Bollhalter[1], W. Mark Brown[6], Margaret R. Savoca[1], Stedman T. Jones[1], Janet Baek[7], Alain G. Bertoni[1,8] and the LIFT Diabetes Research Team

Results: A total of 1102 telephone screens were conducted, resulting in randomization of 260 participants (61.5 % from EMR, mean age 56.3 years, 66.2 % women, 48.1 % non-Hispanic blacks) over a 21-month period, with a yield of 23.6 %. Recruitment yields differed by recruitment method, with referrals having the highest yield (27.5 %). A history of cardiovascular disease was the main health reason for exclusion from the study (16.5 %). An additional 8.9 % were excluded for BMI <25 kg/m^2 (<27 kg/m^2 for insulin users), 5.4 % could not exercise, 5.2 % had an HbA1c >11 %, and 34.9 % were excluded for other non-medical reasons. Exclusion criteria did not appear to differentially affect enrollment in terms of race or ethnicity.

Conclusions: Future clinical studies should tailor their recruitment strategies based on the participant demographics of interest. Efficient methods such as using the EMR system and referrals should be prioritized over labor-intensive, low-yielding methods such as community screenings and mass mailings.

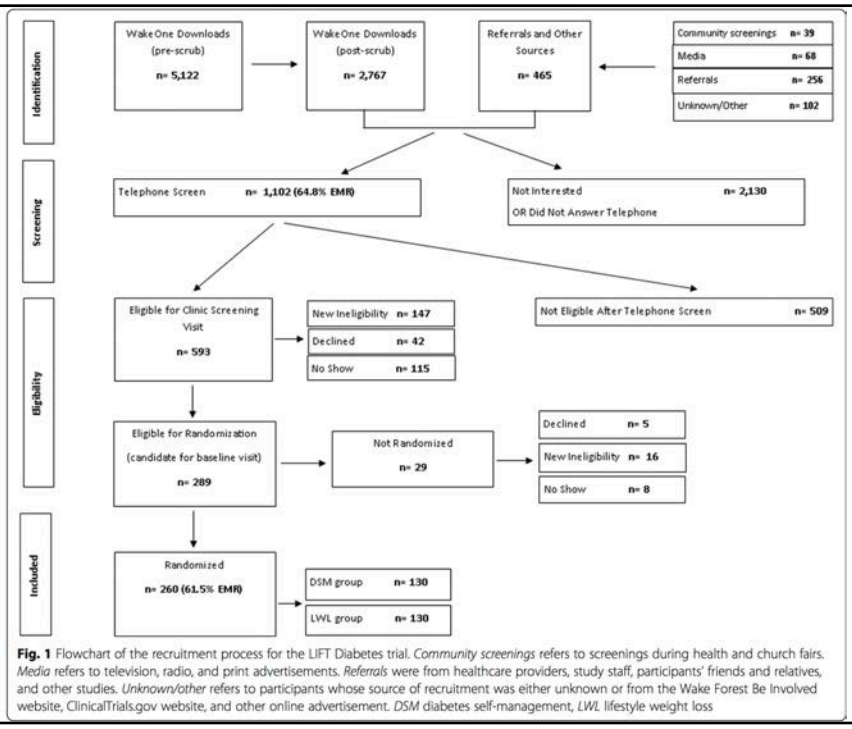


Fig. 1 Flowchart of the recruitment process for the LIFT Diabetes trial. *Community screenings* refers to screenings during health and church fairs. *Media* refers to television, radio, and print advertisements. *Referrals* were from healthcare providers, study staff, participants' friends and relatives, and other studies. *Unknown/other* refers to participants whose source of recruitment was either unknown or from the Wake Forest Be Involved website, ClinicalTrials.gov website, and other online advertisement. *DSM* diabetes self-management, *LWL* lifestyle weight loss

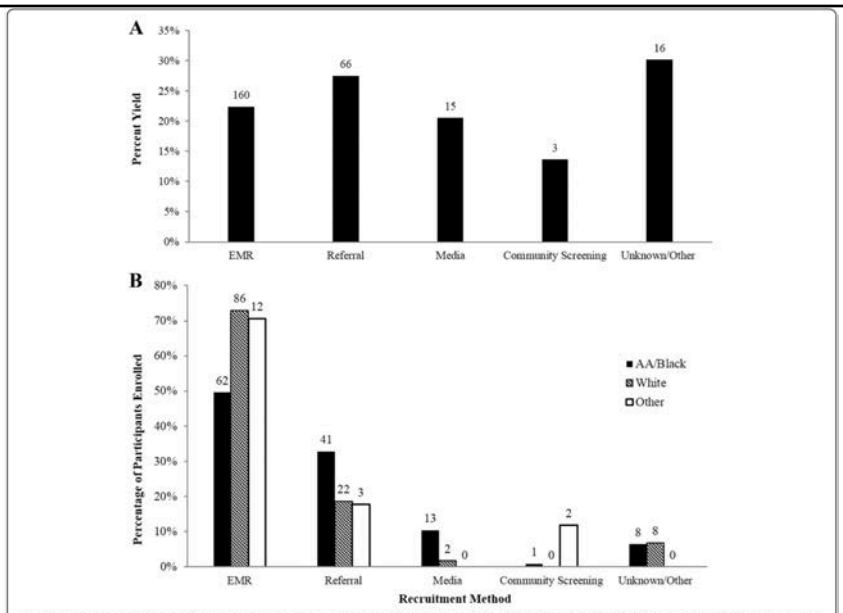


Fig. 3 a Recruitment percent yield. **b** Percentage of participants enrolled. Data are presented by recruitment method. The *horizontal axis* displays the different recruitment methods. The *numbers* on the bars indicate the actual number of participants enrolled for each method. *Community screening* refers to screenings during health and church fairs. *Media* refers to television, radio, and print advertisements. *Referrals* were from healthcare providers, study staff, participants' friends and relatives, and other studies. *Unknown/other* refers to participants whose source of recruitment was either unknown or from the Wake Forest Be Involved website, ClinicalTrials.gov website, and other online advertisement. *AA* African American, *EMR* electronic medical record

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Recruitment methods for survey research: Findings from the Mid-South Clinical Data Research Network

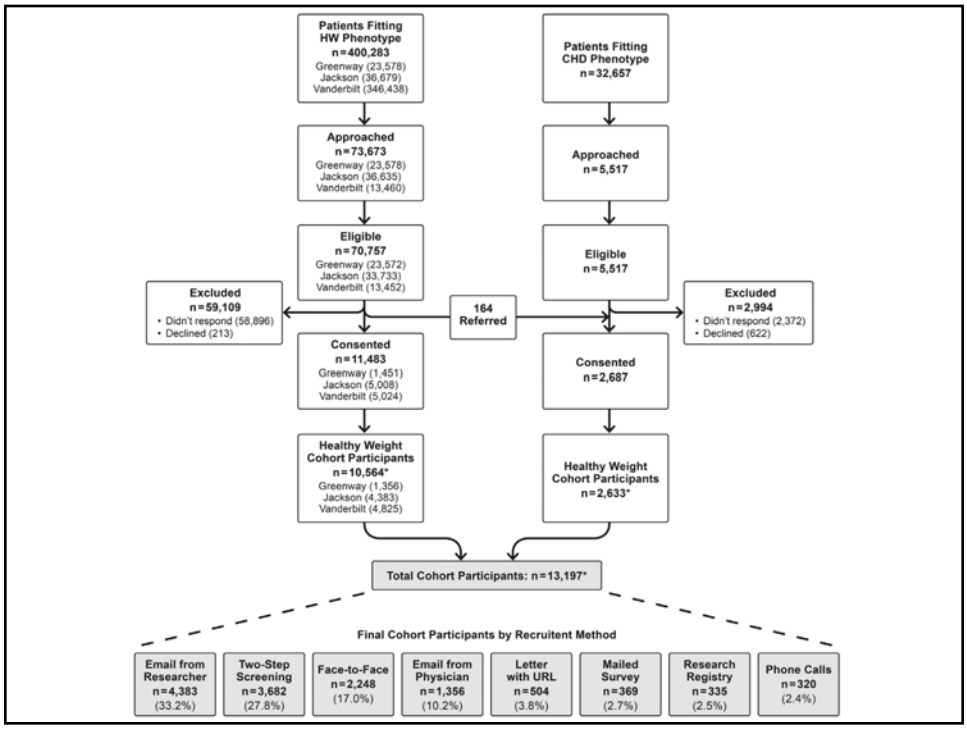
William J. Heerman[a,b,*], Natalie Jackson[a], Christianne L. Roumie[a,b,c], Paul A. Harris[a,b], S. Trent Rosenbloom[b,d], Jill Pulley[a], Consuelo H. Wilkins[e,f,g], Neely A. Williams[e], David Crenshaw[a], Cardella Leak[a], Jon Scherdin[a], Daniel Muñoz[a], Justin Bachmann[a], Russell L. Rothman[a,b], Sunil Kripalani[a,b]

Purpose: The objective of this study was to report survey response rates and demographic characteristics of eight recruitment approaches to determine acceptability and effectiveness of large-scale patient recruitment among various populations.

Methods: We conducted a cross sectional analysis of survey data from two large cohorts. Patients were recruited from the Mid-South Clinical Data Research Network using clinic-based recruitment, research registries, and mail, phone, and email approaches. Response rates are reported as patients who consented for the survey divided by the number of eligible patients approached.

Results: We contacted more than 90,000 patients and 13,197 patients completed surveys. Median age was 56.3 years (IQR 40.9, 67.4). Racial/ethnic distribution was 84.1% White, non-Hispanic; 9.9% Black, non-Hispanic; 1.8% Hispanic; and 4.0% other, non-Hispanic. Face-to-face recruitment had the highest response rate of 94.3%, followed by participants who "opted-in" to a registry (76%). The lowest response rate was for unsolicited emails from the clinic (6.1%). Face-to-face recruitment enrolled a higher percentage of participants who self-identified as Black, non-Hispanic compared to other approaches (18.6% face-to-face vs. 8.4% for email).

Conclusions: Technology-enabled recruitment approaches such as registries and emails are effective for recruiting but may yield less racial/ethnic diversity compared to traditional, more time-intensive approaches.


Patients Fitting HW Phenotype n=400,283
Greenway (23,578)
Jackson (36,679)
Vanderbilt (346,438)
Patients Fitting CHD Phenotype n=32,657
Approached n=73,673
Greenway (23,578)
Jackson (36,635)
Vanderbilt (13,460)
Approached n=5,517
Eligible n=70,757
Greenway (23,572)
Jackson (33,733)
Vanderbilt (13,452)
Eligible n=5,517
Excluded n=59,109
• Didn't respond (58,896)
• Declined (213)
164 Referred
Excluded n=2,994
• Didn't respond (2,372)
• Declined (622)
Consented n=11,483
Greenway (1,451)
Jackson (5,008)
Vanderbilt (5,024)
Consented n=2,687
Healthy Weight Cohort Participants n=10,564*
Greenway (1,356)
Jackson (4,383)
Vanderbilt (4,825)
Healthy Weight Cohort Participants n=2,633*
Total Cohort Participants: n=13,197*
Final Cohort Participants by Recruitent Method
Email from Researcher n=4,383 (33.2%)
Two-Step Screening n=3,682 (27.8%)
Face-to-Face n=2,248 (17.0%)
Email from Physician n=1,356 (10.2%)
Letter with URL n=504 (3.8%)
Mailed Survey n=369 (2.7%)
Research Registry n=335 (2.5%)
Phone Calls n=320 (2.4%)


SAVE YOUR WORK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a knowledgebase for discovering phenotypes from electronic medical records
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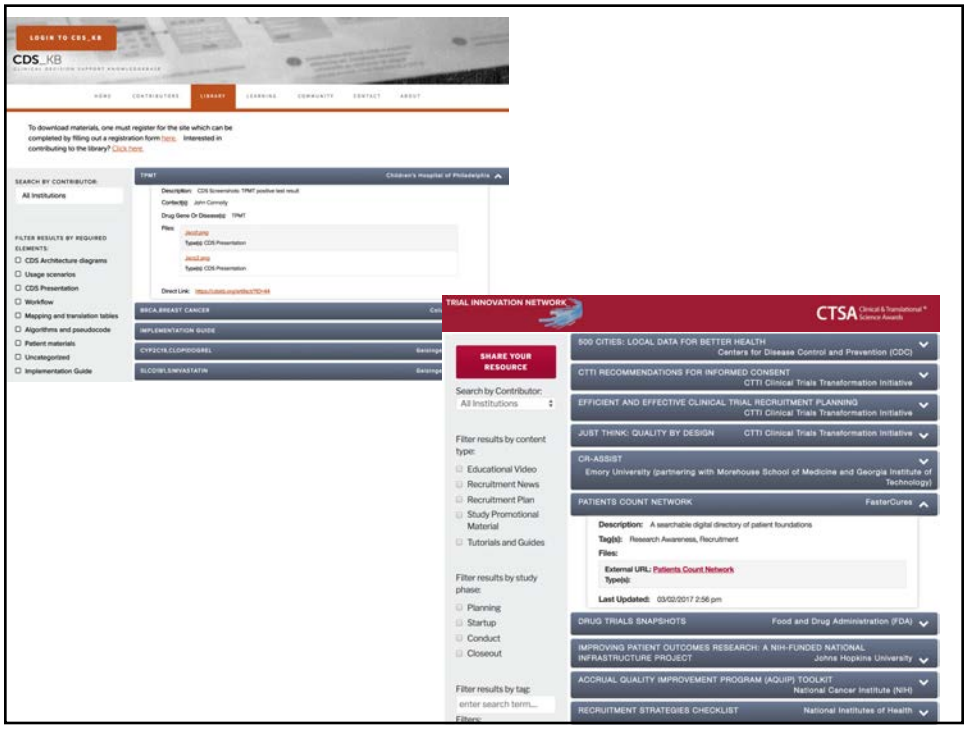
What is the Phenotype KnowledgeBase?
Access Validated Phenotype Algorithms
Validate existing phenotype algorithms on your EMR
Receive feedback and additional validation
Collaborate on Phenotype Algorithms
Publicize your work to better find collaborators
Receive feedback and validation of your algorithm
Share Validated Phenotype Algorithms
One-stop documentation and versioning of validated phenotype algorithms
Tailored searches for algorithms applicable to your EMR system
PheKB
Health Data is becoming an increasing important source for clinical and genomic research. Researchers create and iteratively refine algorithms using structured and unstructured data to better identify cohorts of subjects within the health data.
The Phenotype Knowledgebase website, PheKB, is a collaborative environment to building and validating electronic algorithms to identify characteristics of patients within health data. PheKB was functionally designed to enable such a workflow and has purposefully integrated tools and standards that guide the user in efficiently navigating each of these stages from early stage development to public sharing and reuse. PheKB has tools to enable cross-site collaboration for algorithm development, validation, and sharing for reuse with confidence.
On PheKB you can: View existing algorithms; Enter or create new algorithms; Collaborate with others to create or review algorithms; View implementation details for existing algorithms
Most Recent Phenotypes
Type1 or Type 2 Diabetes Mellitus
Rheumatology Auto-Immune characteristics
Sickle Cell Disease
Consistent Care
Peanut Allergy


LOGIN TO CDS_KB
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To download materials, one must register for the site which can be completed by filling out a registration form here. Interested in contributing to the library? Click here.
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Study Promotional Material
Tutorials and Guides
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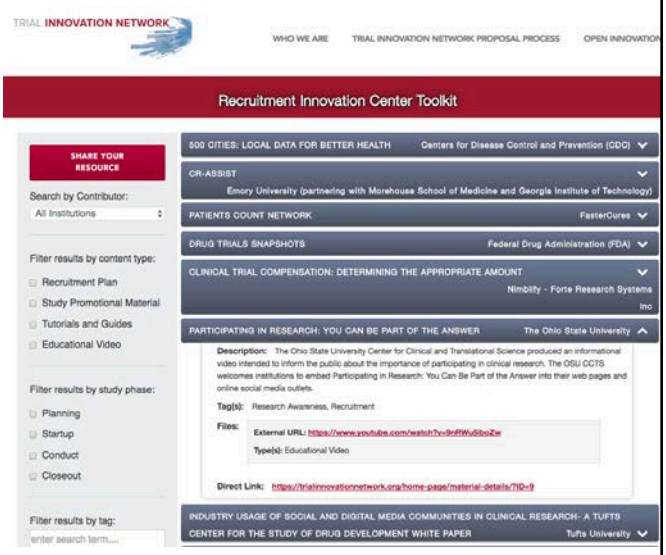
500 CITIES: LOCAL DATA FOR BETTER HEALTH
Centers for Disease Control and Prevention (CDC)
CTTI RECOMMENDATIONS FOR INFORMED CONSENT
CTTI Clinical Trials Transformation Initiative
EFFICIENT AND EFFECTIVE CLINICAL TRIAL RECRUITMENT PLANNING
CTTI Clinical Trials Transformation Initiative
JUST THINK: QUALITY BY DESIGN
CTTI Clinical Trials Transformation Initiative
CR-ASSIST
Emory University (partnering with Morehouse School of Medicine and Georgia Institute of Technology)
PATIENTS COUNT NETWORK
FasterCures
Description: A searchable digital directory of patient foundations
Tag(s): Research Awareness, Recruitment
Files:
External URL: Patients Count Network
Type(s):
Last Updated: 03/02/2017 2:56 pm
DRUG TRIALS SNAPSHOTS
Food and Drug Administration (FDA)
IMPROVING PATIENT OUTCOMES RESEARCH: A NIH-FUNDED NATIONAL INFRASTRUCTURE PROJECT
Johns Hopkins University
ACCRUAL QUALITY IMPROVEMENT PROGRAM (AQUIP) TOOLKIT
National Cancer Institute (NIH)
RECRUITMENT STRATEGIES CHECKLIST
National Institutes of Health

RECRUITMENT INNOVATION CENTER

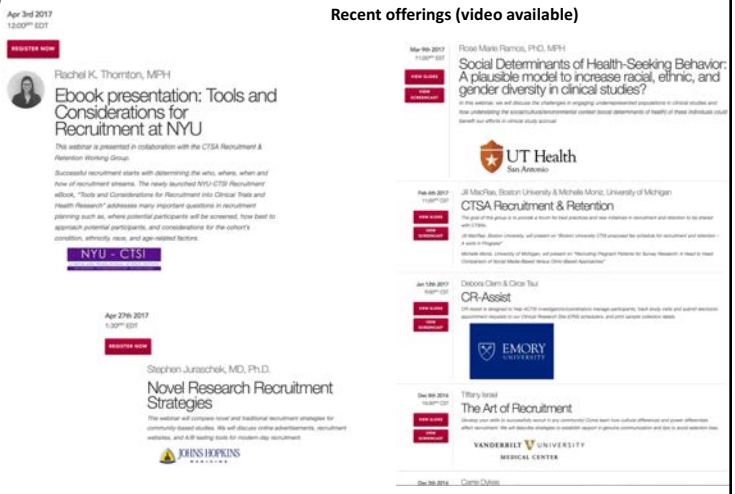
THREE Immediate Opportunities To Collaborate

1



Share materials, tools,
best practices, … www.trialinnovationnetwork.org → → Toolkit

2

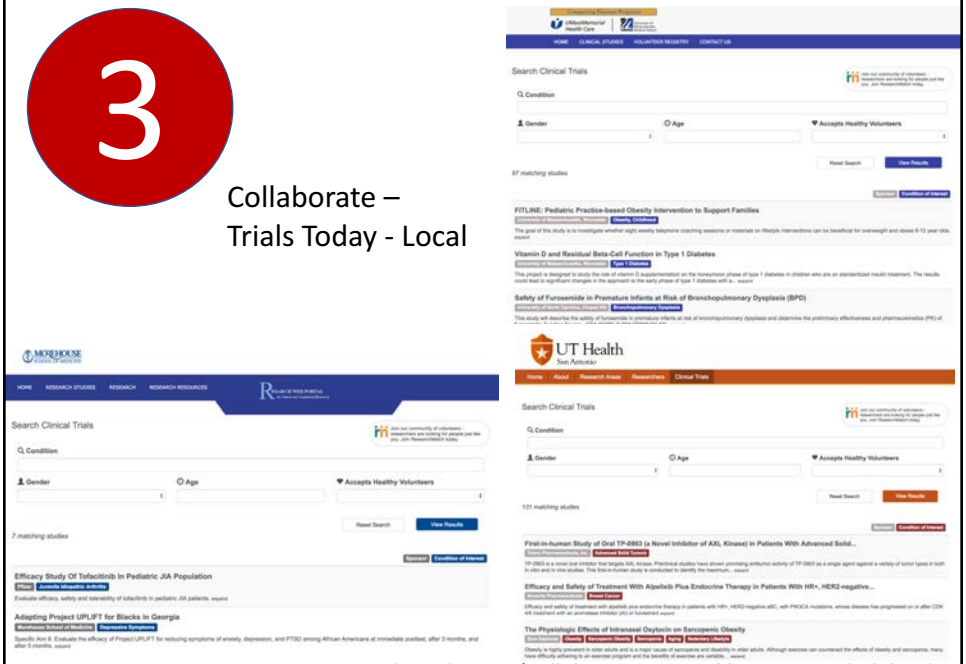


Showcase Your Work --- www.trialinnovationnetwork.org

Give a Webinar (logistics, setup, archival supported by RIC)

3

Collaborate –
Trials Today - Local



Interested in Adopting/Collaborating? paul.harris@vanderbilt.edu


THANK
YOU!