VINCI Services

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Overview

1. VINCI
2. Data in VINCI
3. VINCI Services
4. Feasibilities
5. Data Needs Assessment
6. Patients List
7. DART for the Patients List
8. Research Project Life Cycle

Objective

➢ Type of data assistance the VINCI Services team provides for the VA researchers

➢ Requirements for the each service

➢ How to request services from VINCI

What is your primary role in research?

1. Investigator
2. Study coordinator
3. Programmer
4. Statistician
5. Other

How often have you used VINCI Services?

1. Never used
2. One time
3. Multiple times

What types of services from VINCI have you used?

1. Never used
2. Feasibility
3. Patient List
4. Data needs assessment
5. Multiple services

VINCI

The VA Informatics and Computing Infrastructure (VINCI) is a major informatics initiative of the Department of Veterans Affairs (VA) that provides a secure, central analytic platform for performing research and supporting clinical operations activities. It is a partnership between the VA Office of Information Technology (OI&T) and the Veterans Health Administration Office of Research and Development (VHA ORD). VINCI includes a cluster of servers for securely hosting suites of databases integrated from select national VA data sources.

VINCI has data on more than <u>22 million patients</u> receiving care at over 1,400 medical centers, outpatient clinics, nursing homes, and domiciliaries. Most data originates from the extensively used Veterans Health Information Systems and Technology Architecture (VistA), the VA electronic medical record system.

➢ Feasibility

➢ Data Needs Assessment

➢ Patient List

Feasibility

➢ Feasibilities provide aggregate counts for researchers during **the preparatory to research phase**. The deliverables result in descriptive statistics and summarized counts to assist in grant and IRB applications.

➢ Feasibilities help to understand **cohort size and structure**

➢ Feasibilities help to understand **impact of each criteria to cohort size and structure**

➢ Feasibilities result **cannot** be used for any publication

➢ **No regulatory documents** are required

Feasibility

Inclusion/exclusion criteria

o Location (nationwide or some specific location
o Time frame
o Age/gender/other limitation
o Diagnosis (ICD9*/10 codes (*VA uses ICD10 codes since October 2015. If time frame more than 3 years, please, provide both))
o Procedures (CPT codes or/and ICD-PC)
o Lab test. (topography, units, range)
o Medications (list of all generic and brand names, strength and route of administration)

Break downs

o Locations
o Time periods
o Age groups
o BMI groups
o Race
o Etc.

Attrition table

This is a funnel analysis. Numbers presented in column D are based on the number in the row above. For example, Row 8 will be less than or equal to the number in Row7

Criteria Definition	Query Definition	Number of distinct patients remaining	
Inclusion criteria			
Number of patients seen outpatient or inpatient with diabetes type 2 (ICD10 code) at Salt Lake City (station 660) from 1/1/2018-present			
Number of patients had prescribed insulin/type 2 diabetes medication (list of medication) at 1/1/2018-present			
Exclusion Criteria			**# Excluded**
Number of patients with serious health conditions (ICD10 codes) at 1/1/2018-present			

Feasibility

Attrition table _ Result

This is a funnel analysis. Numbers presented in column D are based on the number in the row above. For example, Row 8 will be less than or equal to the number in Row7
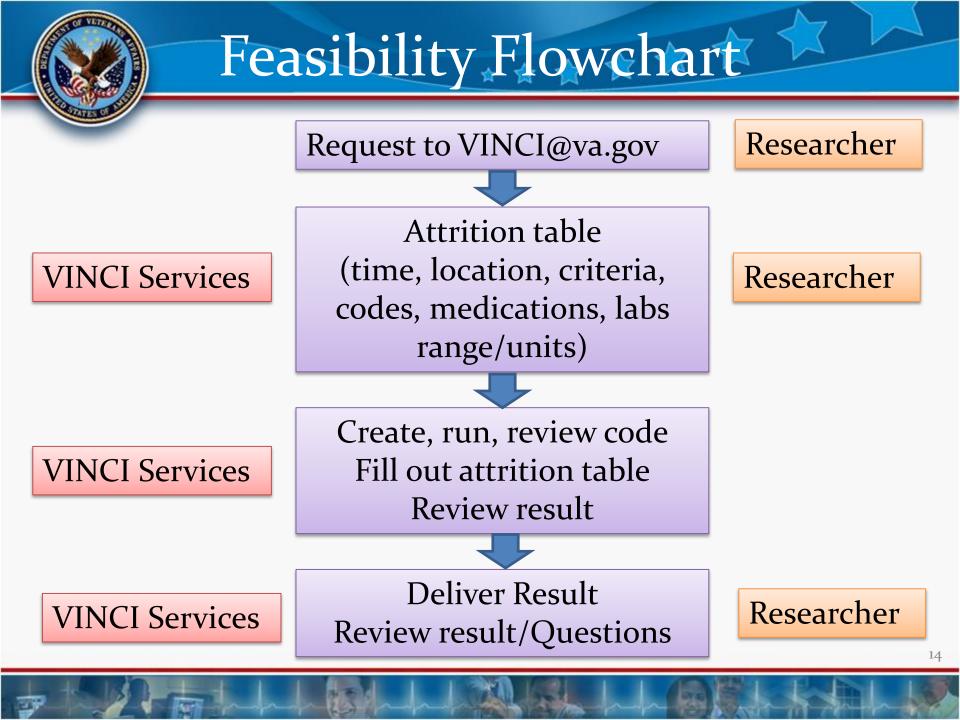
Criteria Definition	Query Definition	Number of distinct patients remaining	
Inclusion criteria			
Number of patients seen outpatient or inpatient with diabetes type 2 (ICD10 code) at Salt Lake City (station 660) from 1/1/2018-present	Distinct patients seen inpatient or outpatient for diabetes type 2 at SLC from 1/1/2018 to present	14,320	
Number of patients had prescribed insulin/type 2 diabetes medication (list of medication) at 1/1/2018-present	Distinct patients from D7 with inpatient or outpatient insulin and/or type 2 diabetes medications from any location from 1/1/2018 to present	10,717	
Exclusion Criteria			**# Excluded**
Number of patients with serious health conditions (ICD10 codes) at 1/1/2018-present	Distinct patients from D8 without serious health conditions diagnosed inpatient or outpatient at any location from 1/1/2018 to present	5,827	4890

Feasibility Flowchart

Request to VINCI@va.gov — Researcher

Attrition table
(time, location, criteria, codes, medications, labs range/units)

VINCI Services — Researcher

Create, run, review code
Fill out attrition table
Review result

VINCI Services

Deliver Result
Review result/Questions

VINCI Services — Researcher

Data Needs Assessment (DNA)

VINCI Services supports VA research by assisting customers with Data Needs questions (DNA) relating to the VA Corporate Data Warehouse (CDW) and other VA data sources.
These questions range from
- ✓ data availability
- ✓ data location
- ✓ data definitions
- ✓ assistance with completing the DART application
- ✓ assistance with completing CDW-domain checklist
- ✓ assistance with IRB protocol preparation
- ✓ etc.

Electronic Medical Record (EMR)-driven recruitment support supplements traditional patient recruiting methods by leveraging patient data stored in the VA EMR

IRB approved prospective projects:
- Clinical trials (intervention: drugs, devises, tests, contact, etc.)
- Cohort studies
  - observational study
  - survey study

Environment and security VINCI descriptions for use with IRB packages.

https://vaww.vinci.med.va.gov/VinciCentral/NewToVinci/IRBChecklist

The Data Access Request Tracker (DART)

http://vaww.vhadataportal.med.va.gov/DataAccess/DARTRequestProcess.aspx#SubmitRequest

Required Documents

- Research Protocol
- Research Study Institutional Review Board (IRB) Approval Letter
- Sample Informed Consent
- Research and Development (RD) Committee Approval Letter
- IRB Approval Waiver of HIPAA-Compliant Authorization*
- Research Request Memo*
- CDW-Domain Checklist*
- Request to Real SSN Access (if needed)*

Blank Documents (*)

- Research Request Memo*

- IRB Approval Waiver of HIPAA-Compliant Authorization*

- CDW-Domain Checklist*

- Request to Real SSN Access (if needed)*

http://vaww.vhadataportal.med.va.gov/DataAccess/DARTRequestProcess.aspx#DocumentsAndForms
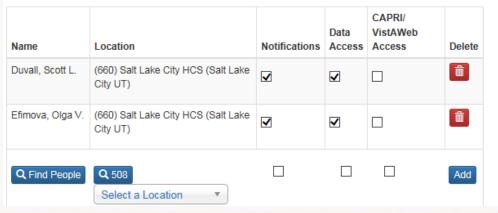
Select
"Research Data Access"!

Participants

- Select "Notification" and "Data access"

- Select "CAPRI/VistAWeb Access" only for manual chart review on national level

Patients List - DART

Data Sources

2016-02-014-D   r2

:≡ Data Sources

Data Storage Location *

☑ VINCI
☐ Local VA Server Location

Will data be transferred external to the VHA? *

Currently CDW cannot approve a research request that would include disclosing the CDW data (identifiable or de-identified) outside of VHA without a signed research consent and HIPAA authorization from the individual because of the risk of or state agency disclosing information on the individual back to VA per SOR 34VA12, a DUA between the PI and the external agency must be submitted with the DART application.

◉ No
○ Yes (DUA is required)

IDENTIFIERS (More about Identifiers)

☑ Real SSN
☐ Scrambled SSN
☐ Identifiable data but no real or scrambled SSNs

REQUESTED DATA SOURCES

Corporate Data Warehouse (CDW)

SQL Format
    ☑ CDW Production Domains
    ☐ CDW Raw Domains
    ☐ CDW MCA (formerly DSS) NDE
    ☐ MedSAS Files Including VetsNet Files
    ☐ TIU Text Notes (Requires Real SSN Approval)
    ☐ Vital Status Files (Includes BIRLS)

SAS Format (no longer available – same data available in SQL format above)
    ☐ BIRLS
    ☐ MCA (formerly DSS) NDE (legacy)
    ☐ Vital Status Files with Scrambled SSN
    ☐ Vital Status File Real SSN Crosswalk File

Mainframe - Access

☐ BIRLS Real SSN (110JJ02)
☐ MedSAS Including VetsNet Files for National Level Real SSN (110TT01)
☐ MedSAS Files for VISN Level Real SSN (110TT05)
☐ Vital Status Files with Scrambled SSN (110NN06)
☐ Vital Status File Real SSN Crosswalk File (110TT20)

Other Data

☐ CAPRI/VistAWeb (Individuals needing Capri/VistA Web access are selected on the participants page and require real SSN approval)
☐ Care Assessment Need (CAN) Score (Requires Scrambled SSN Level Access)
☐ Health Economics Resource Center (HERC) Average Cost Data
☐ Health Economics Resource Center (HERC) V21 and Nosos Risk Scores Data
☐ Homeless Registry
☐ Legacy Data Warehouses (i.e. VISN 21)
☐ MCA (formerly DSS) Web Reports
☐ OEF/OIF Roster File (DUA required for internal data distribution/use)
☐ Patient Aligned Care Team (PACT) Implementation Index (PI2)
☐ Surgery Quality Data Users Group (SQDUG)
☐ VSSC Web Reports

Data Access Systems

☐ SAS Grid

Does your study require Informed Consent and HIPAA Authorization?

◉ Yes
○ No

Does your study require a HIPAA Waiver?

○ Yes
◉ No

Data Sources

Data Storage Location *

☑ VINCI
☑ Local VA Server Location

Name of facility *

Address *

Building

Room #

IDENTIFIERS (More about identifiers)

☑ Real SSN

☐ Scrambled SSN

☐ Identifiable data but no real or scrambled SSNs

REQUESTED DATA SOURCES

Corporate Data Warehouse (CDW)

SQL Format

☑ CDW Production Domains

☐ CDW Raw Domains

☐ CDW MCA (formerly DSS) NDE

☐ MedSAS Files including VetsNet Files

☐ TIU Text Notes (Requires Real SSN Approval)

☐ Vital Status Files (includes BIRLS)

Data Sources

Does your study require Informed Consent and HIPAA Authorization?

- ⦿ Yes
- ◯ No

Does your study require a HIPAA Waiver?

- ⦿ Yes
- ◯ No

Documents

REQUIRED DOCUMENTS

⊬ (580) Houston, TX (Primary Site)

Research Request Memo
Required for Vital Status File Real SSN Crosswalk File (110TT20), Vital Status Files with Scrambled SSN (110NN06), CDW Production Domains, CDW Raw Domains, TIU Text Notes, Vital Status, Health Economics Resource Center (HERC) Average Cost Data, Health Economics Resource Center (HERC) V21 and Nosos Risk Scores Data

Research Study Institutional Review Board (IRB) Approval Letter
Required for Vital Status File Real SSN Crosswalk File (110TT20), Vital Status Files with Scrambled SSN (110NN06), CDW Production Domains, CDW Raw Domains, TIU Text Notes, Vital Status, Health Economics Resource Center (HERC) Average Cost Data, Health Economics Resource Center (HERC) V21 and Nosos Risk Scores Data

Sample Informed Consent and HIPAA Authorization
Required for Vital Status File Real SSN Crosswalk File (110TT20), Vital Status Files with Scrambled SSN (110NN06), CDW Production Domains, CDW Raw Domains, TIU Text Notes, Vital Status, Health Economics Resource Center (HERC) Average Cost Data, Health Economics Resource Center (HERC) V21 and Nosos Risk Scores Data

Research and Development (RD) Committee Approval Letter
Required for Vital Status File Real SSN Crosswalk File (110TT20), Vital Status Files with Scrambled SSN (110NN06), CDW Production Domains, CDW Raw Domains, TIU Text Notes, Vital Status, Health Economics Resource Center (HERC) Average Cost Data, Health Economics Resource Center (HERC) V21 and Nosos Risk Scores Data

IRB Approval of Waiver of HIPAA-Compliant Authorization
Required for Vital Status File Real SSN Crosswalk File (110TT20), Vital Status Files with Scrambled SSN (110NN06), CDW Production Domains, CDW Raw Domains, TIU Text Notes, Vital Status, Health Economics Resource Center (HERC) Average Cost Data, Health Economics Resource Center (HERC) V21 and Nosos Risk Scores Data

Research Protocol
Required for Vital Status File Real SSN Crosswalk File (110TT20), Vital Status Files with Scrambled SSN (110NN06), CDW Production Domains, CDW Raw Domains, TIU Text Notes, Vital Status, Health Economics Resource Center (HERC) Average Cost Data, Health Economics Resource Center (HERC) V21 and Nosos Risk Scores Data

CDW-Domain Checklist
Required for CDW Production Domains, CDW Raw Domains, Health Economics Resource Center (HERC) Average Cost Data, Health Economics Resource Center (HERC) V21 and Nosos Risk Scores Data

Real SSN Access Request
Required for Vital Status File Real SSN Crosswalk File (110TT20), CDW Production Domains, CDW Raw Domains, TIU Text Notes, Vital Status, Health Economics Resource Center (HERC) Average Cost Data, Health Economics Resource Center (HERC) V21 and Nosos Risk Scores Data

Research Request Memo

We are requesting list of patients meet Inclusion/Exclusion criteria:
1.
2.
3.
Etc.

With the following patient information:
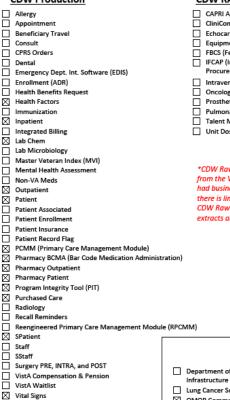- Patient name
- DOB
- SSN
- Address
- Etc.

Memorandum

Department of
Veterans Affairs

Date:

From: Principal Investigator   "Insert Name of Principal Investigator"

Subj: Research Data Request Memo for: "Tracking Number - Name of Protocol"

To: Director, National Data Systems

The following information is required and all signatures must be obtained before any review of this request can take place:

Are all participants requesting access a VA employees or WOC employees? ☒Yes ☐No
Is this request for data use for a VA research study (includes pilot studies)?: ☒Yes ☐No
Is this request for activities preparatory to research? ☐Yes ☒No
Select the type(s) of data needed: ☒Real SSN ☐Scrambled SSN ☐PHI but No SSN
Is access to CAPRI / VistAWeb being requested? ☐Yes ☒No
Is access to VSSC and/or MCA Web Reports being requested? ☐Yes ☒No
Will any requested data be transferred outside of the VA? ☐Yes ☒No
Will the data be stored in the VINCI Environment? ☐Yes ☐No ☒Both

Describe where the data will be stored within the VA network by providing the following information:

Facility/Company Name

Building Number   Room Number

Street Address

City   State   Zip Code

Country

Please address the following five items in the body of the memo below:
1. Describe how the data will be transferred, (i.e. electronic, cd, etc.) between the Transferring Agency and Custodian and the methods that you will take to secure the transmission of the data.
2. Describe how the data will be securely retained with the Custodian's network.
3. Describe how and by whom the data will be accessed.
4. Describe how long the data will be retained after project completion and how the data will be destroyed.
5. Describe how you will maintain an auditing of the activity (users and location) of the data.

Please describe the data you are requesting. The data requested must reflect data discussed in the protocol or HIPAA waiver if applicable and selected in DART.
Provide a high level summary of how the requested data will be used in the research study.

Health Factors
Inpatient
Lab Chem
Outpatient
Patient
Pharmacy Outpatient
Pharmacy Patient
SPatient
Vital Signs
OMOP

CDW DOMAIN CHECKLIST

CDW Production
- ☐ Allergy
- ☐ Appointment
- ☐ Beneficiary Travel
- ☐ Consult
- ☐ CPRS Orders
- ☐ Dental
- ☐ Emergency Dept. Int. Software (EDIS)
- ☐ Enrollment (ADR)
- ☐ Health Benefits Request
- ☒ Health Factors
- ☐ Immunization
- ☒ Inpatient
- ☐ Integrated Billing
- ☒ Lab Chem
- ☐ Lab Microbiology
- ☐ Master Veteran Index (MVI)
- ☐ Mental Health Assessment
- ☐ Non-VA Meds
- ☒ Outpatient
- ☒ Patient
- ☐ Patient Associated
- ☐ Patient Enrollment
- ☐ Patient Insurance
- ☐ Patient Record Flag
- ☒ PCMM (Primary Care Management Module)
- ☒ Pharmacy BCMA (Bar Code Medication Administration)
- ☒ Pharmacy Outpatient
- ☒ Pharmacy Patient
- ☒ Program Integrity Tool (PIT)
- ☒ Purchased Care
- ☐ Radiology
- ☐ Recall Reminders
- ☐ Reengineered Primary Care Management Module (RPCMM)
- ☒ SPatient
- ☐ Staff
- ☐ SStaff
- ☐ Surgery PRE, INTRA, and POST
- ☐ VistA Compensation & Pension
- ☐ VistA Waitlist
- ☒ Vital Signs
- ☐ Women's Health

CDW RAW*
- ☐ CAPRI Audit Trail table
- ☐ CliniComp
- ☐ Echocardiogram
- ☐ Equipment Inventory
- ☐ FBCS (Fee Basis Claim System)
- ☐ IFCAP (Integrated Funds Control, Accounting, and Procurement)
- ☐ Intravenous meds (IV)
- ☐ Oncology
- ☐ Prosthetics
- ☐ Pulmonary Function Test (PFT)
- ☐ Talent Management System (TMS)
- ☐ Unit Dose (Pharmacy)

CDW Raw data is data that has been pulled directly from the VistA sites and the data has not been verified or had business rules applied. It may not be current and there is limited documentation for users. Requests for CDW Raw data require additional time for creating data extracts and it is more difficult for studies to use.

Other Data
- ☐ Department of Defense and Department of Veterans Affairs Infrastructure for Clinical Intelligence (DAVINCI)
- ☐ Lung Cancer Screening Demonstration Cohort
- ☒ OMOP Common Data Model (CDW Production/Raw Source)
- ☐ PSSG Geocoded Files
- ☐ SAS Fee
- ☐ VINCI NLP Output

For additional information about the domains, please refer to the link below:
http://vaww.virec.research.va.gov/CDW/Documentation.htm

CDW Checklist V 6.3 November 13, 2018. This document revision supersedes any previous versions.

<u>Inclusion/Exclusion criteria</u>

- Location (nationwide or some specific location
- Time frame
- Age/gender limitation
- **Distance from current address to VAMC**
- Diagnosis. ICD9*/10 codes (*VA uses ICD10 codes since October 2015. If time frame more than 3 years, please, provide both)
- Procedures. CPT codes or/and ICD-PC
- Lab test. Units, range
- Medications (list of all generic and brand names, strength and route of administration)

Note! Use variables from structured data only

Patients List

List of deliverable variables:
- ✓ Patient name
- ✓ DOB
- ✓ SSN/Last 4
- ✓ Address
- ✓ Phone
- ✓ Date/location of upcoming appointment
- ✓ Etc.

Limitation (will not be delivered)
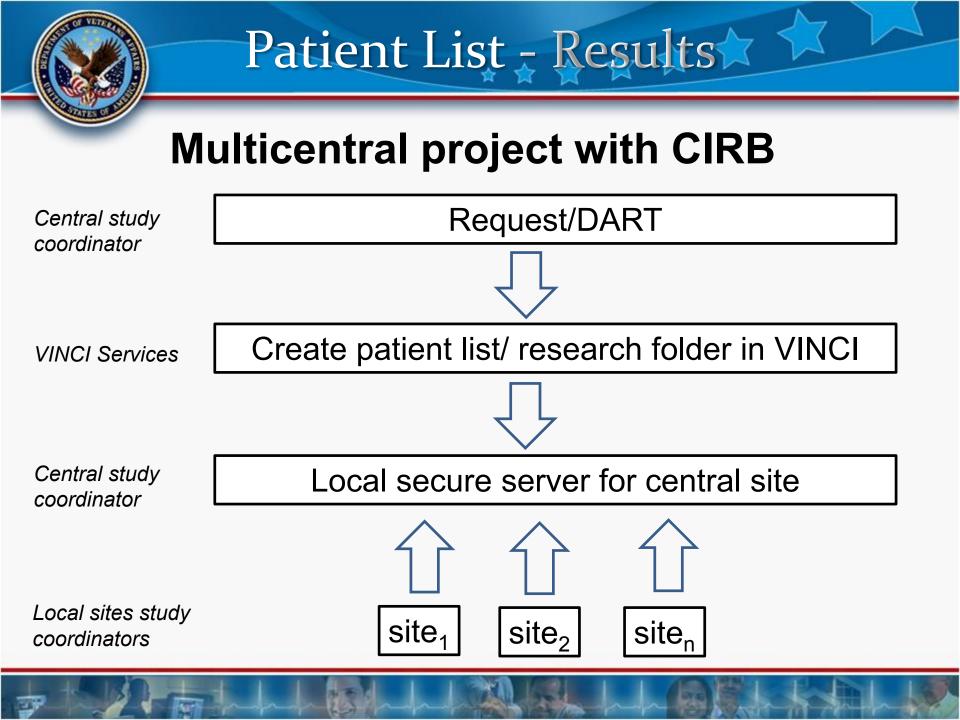- ✓ Problem list
- ✓ Current medications list

- Excel file

- Instructions to access VINCI

- Instructions to download file to local secure server

<u>Occurrence:</u>

➤ One time
➤ On regular basis (monthly, quarterly, etc.)
➤ By Demand

Multicentral project with CIRB

Central study coordinator

Request/DART

VINCI Services

Create patient list/ research folder in VINCI

Central study coordinator

Local secure server for central site

Local sites study coordinators

$site_1$	$site_2$	$site_n$

Patient List Flowchart

VINCI Services

Feasibility

Researcher

Regulatory Documents
Protocol, IRB, R&D, DART

Researcher

VINCI Services

Attrition Table for patient list

Researcher

VINCI Services

Create , Review Patients List

VINCI Services

Deliver Patients List

Review/Utilize Patients List

Researcher

Research Project Life Cycle

Research Idea

DNA/ Feasibility

Project Protocol or/and Grant application
Regulatory process (IRB,R&D)

DNA

Request to access data (DART)

DNA

DART approval

DNA

Project
Retrospective
Prospective

Prospective
project
(patient list)

➤ Feasibility (cohort size and structure/ no regulatory documents/ cannot be used for publications

➤ Data Needs Assessment (data and applications questions, assistance)

➤ Patient List (IRB-approved prospective studies, can be created on regular base)

VINCI@va.gov

Feedback

We appreciate your opinions and feedback.

Please, take a moment to complete
our customer satisfaction survey.

Click **here** to access

QUESTIONS?

THANK YOU!