DATA ACCESS MINISERIES

FY25 Session #4:

Requesting Data Preparatory to Research

November 6, 2024

Presenter: Olga Efimova, MD, PhD, VINCI

DATA ACCESS CYBERSEMINAR MINISERIES

Informational seminars to help VA researchers access VA databases.

Topics Include:

VA Data Access Requirements for Research

Requesting Research Data Access Using DART

VA Data Access Preparatory to Research Requirements

Preparatory to Research Project

VA Data Access Requirements for Operations

UPCOMING DATA ACCESS SESSIONS

Date	Topic
9/4/24	VA Data Access Requirements for Research
10/2/24	Requesting Research Data Access Using DART
10/10/24	VA Data Access Preparatory to Research Requirements
11/6/24	Preparatory to Research Project
11/14/24	VA Data Access Requirements for Operations

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page for more
information & registration
links.

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Cyberseminar Archive
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sessions.

Where can I download a copy of the slides?

SAMPLE EMAIL

A Practical Approach to Working with VA-Purchased Community Care Data

Thursday, October 13, 2022
2:00 PM | (UTC-04:00) Eastern Time (US & Canada) | 1 hr

Please download today's slides
Please click here for today's live captions

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https://veteransaffairs.webex.com/veteransaffairs/j.php?

Sponsored by: **VIReC** **VINCI**

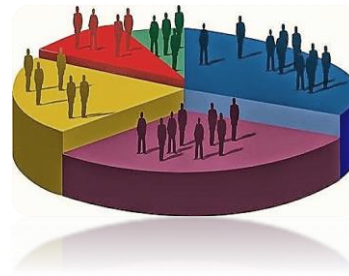# FY25 Session #4:

Requesting Data Preparatory to Research

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Poll #1:

*What is your primary **role** in projects using VA data?*

- Investigator, PI, Co-I

- Statistician, methodologist, biostatistician

- Data manager, analyst, or programmer

- Project coordinator

- Other – please describe via the chat function

Poll #2:

How many years of experience working with VA data?

- None – I'm brand new to this!

- One year or less

- More than 1, less than 3 years

- At least 3, less than 7 years

- At least 7, less than 10 years

- 10 years or more

Session roadmap

- ✓ **VINCI services for preparatory to research activities.**

- ✓ **Steps for submitting a preparatory to research DART request.**

- ✓ **Data description in a research protocol.**

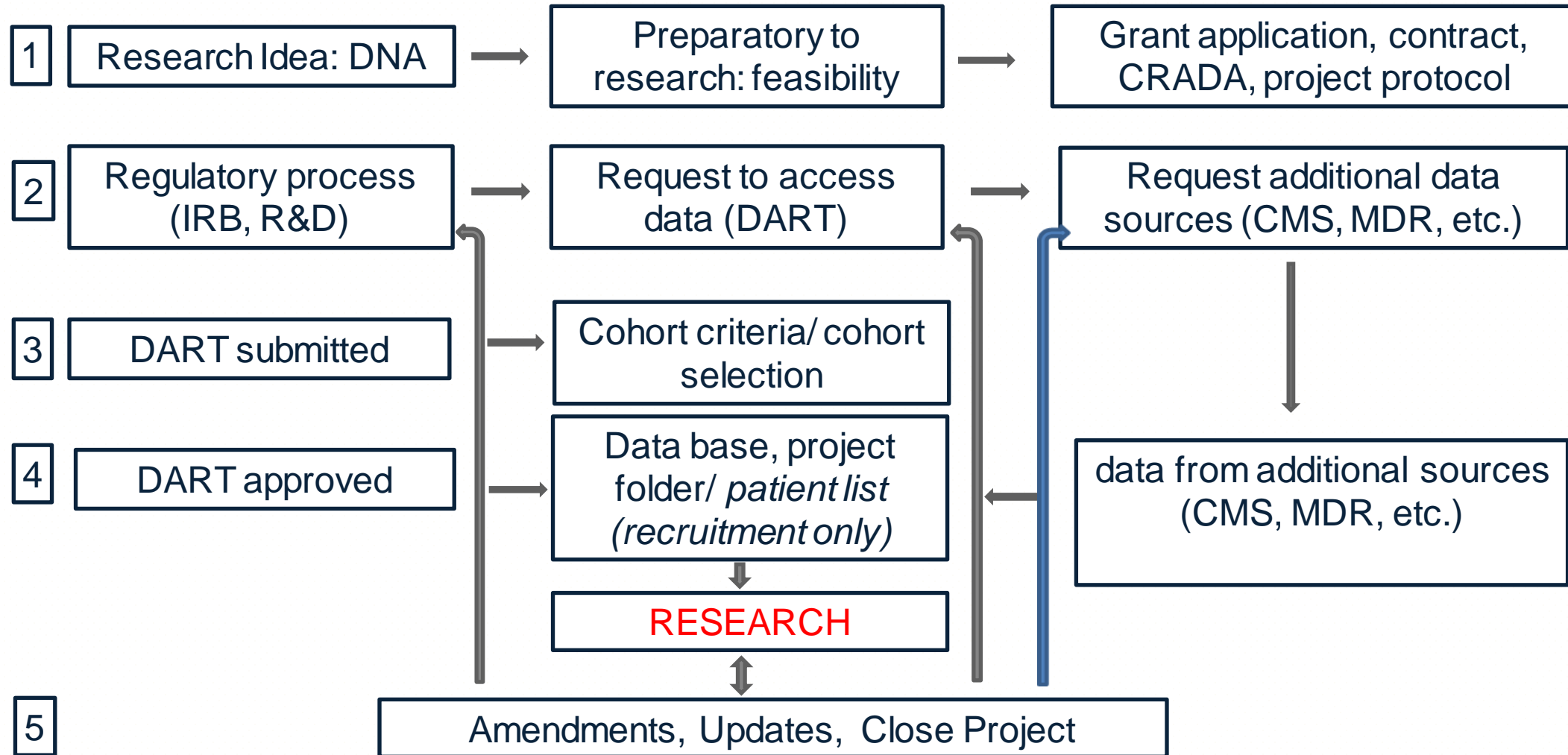- ✓ **Suggestions for establishing a research study team.**

VINCI DATA

✓VINCI data base has data on more than <u>26 million patients </u>receiving care at over 1,400 medical centers (inpatient), outpatient clinics, nursing homes, and non-VA medical centers

✓Most data originates from the extensively used the VA electronic medical record systems (Veterans Health Information Systems and Technology Architecture (VistA) and Millennium HER) and from other data sources

✓SQL (language designed to store, extract data) is using to pull variables of interest from data sources for the cohort

✓Data <u>is not available in VINCI, but can be incorporated in project data base </u>: cause of death (MDR), Medicaid/Medicare data (CMS), etc.

✓Data <u>is not available in VINCI: </u>images

✓Data is <u>available only in text</u>: pathology report, radiology report, medical providers notes, etc. (TIU notes, CPRS, CAPRI/JLV)

Projects

- **Operational project/ Quality Assurance/Improvement project** (operational studies; result cannot be published in open sources)

- ## Research projects

  ➤ Retrospective project

  ➤ Prospective projects:

  - Clinical trial (intervention: drugs, devises, tests, contact, etc.)

  - Cohort study

    - observational study

    - survey study

  ➤ Combination of prospective & retrospective

Research Project

1 | Research Idea: DNA → Preparatory to research: feasibility → Grant application, contract, CRADA, project protocol

2 | Regulatory process (IRB, R&D) → Request to access data (DART) → Request additional data sources (CMS, MDR, etc.)

3 | DART submitted → Cohort criteria/ cohort selection

4 | DART approved → Data base, project folder/ *patient list (recruitment only)* → RESEARCH

data from additional sources (CMS, MDR, etc.)

5 | Amendments, Updates, Close Project

Preparatory to research _ 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
- ✓ Language for the proposal/ IRB protocol preparation,
- ✓ assistance with completing the DART application
- ✓ assistance with completing DART forms including CDW-domain checklist,
- ✓ Other questions.

Request DNA consultation at vinci@va.gov

Preparatory to research _ DNA
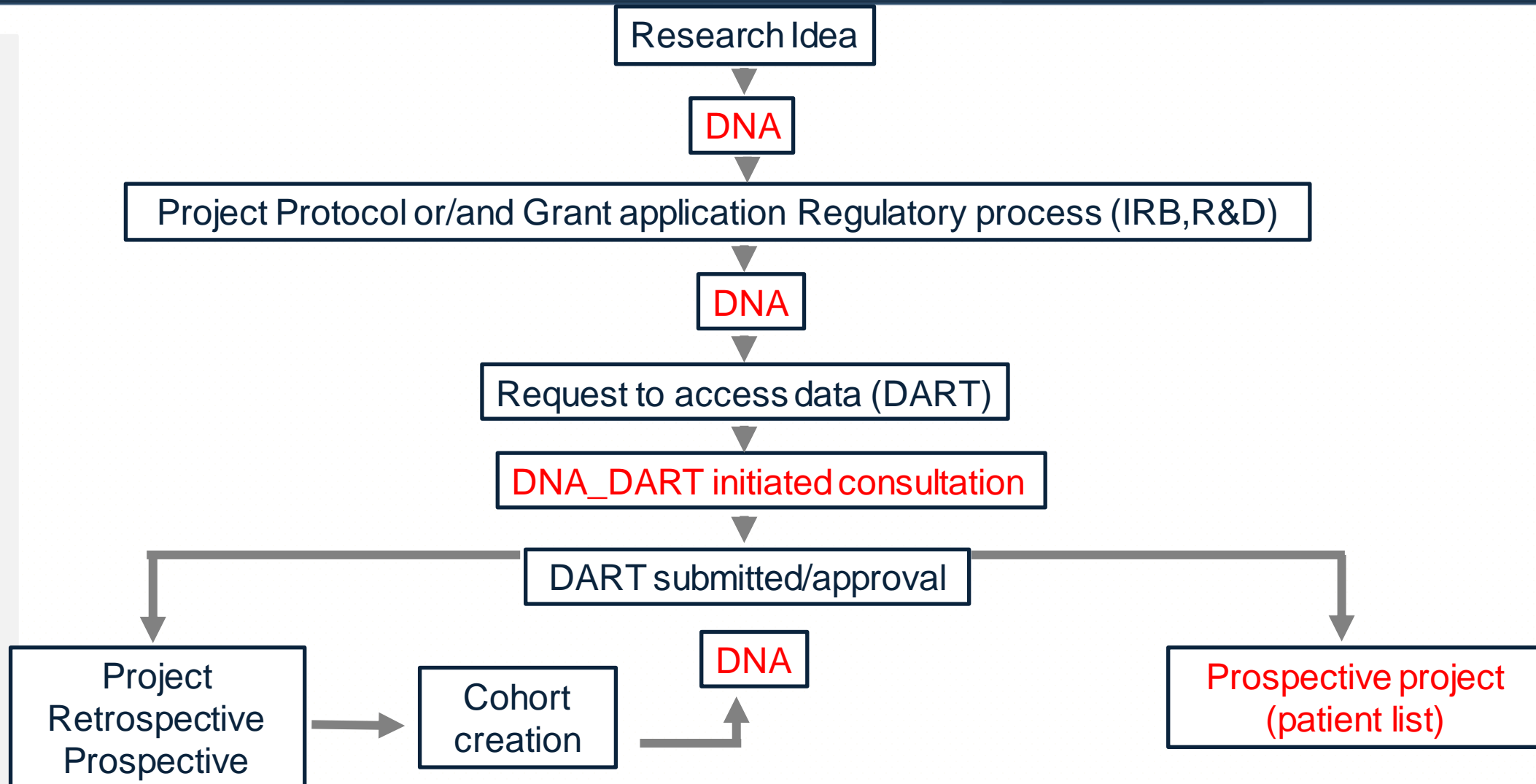
Preparatory to Research _ Feasibility

Preparatory to Research _ Feasibility

➤ Feasibilities provide aggregate counts for researchers during **the preparatory-to-research phase**. The deliverables result in 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**

➤ **No regulatory documents** are required

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

➤ Can be conducted by VINCI Services team (no DART)

➤ Request feasibility count at vinci@va.gov

Preparatory to Research _ 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 7 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.

Preparatory to Research _ Feasibility

	A	B	C	D	E	F	G
1		**FEAS_**					
2		This is a funnel analysis. Numbers presented in column D are based on the number in the row above.					
3		For example, Row 8 will be less than or equal to the number in Row7					
4							

	Criteria Definition	Care Setting	Location	Time range	Query Definition	Number of distinct patients
Inclusion criteria						
Number of Veterans seen outpatient, inpatient, fee basis at Salt Lake City VA (station 660) from 1/1/2018-present						
Number of patients from G7 seen outpatient, inpatient, fee basis with diabetes type 2 (ICD10 code) at Salt Lake City VA (station 660) from 1/1/2018-present	outpatient, inpatient, fee basis	Salt Lake City VA (station 660)	1/1/2018-present		
Number of patients from G8 had prescribed insulin/type 2 diabetes medication (list of medication) at 1/1/2018-present						
Exclusion criteria						
Number of patients with serious health conditions (ICD10 codes) at 1/1/2018-present	outpatient, inpatient, fee basis	nationwide	1/1/2018-present		

Preparatory to Research Feasibility Flowchart

Request to VINCI@va.gov

Researcher

VINCI Services

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

Researcher

VINCI Services

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

VINCI Services

Deliver Result
Review result/Questions
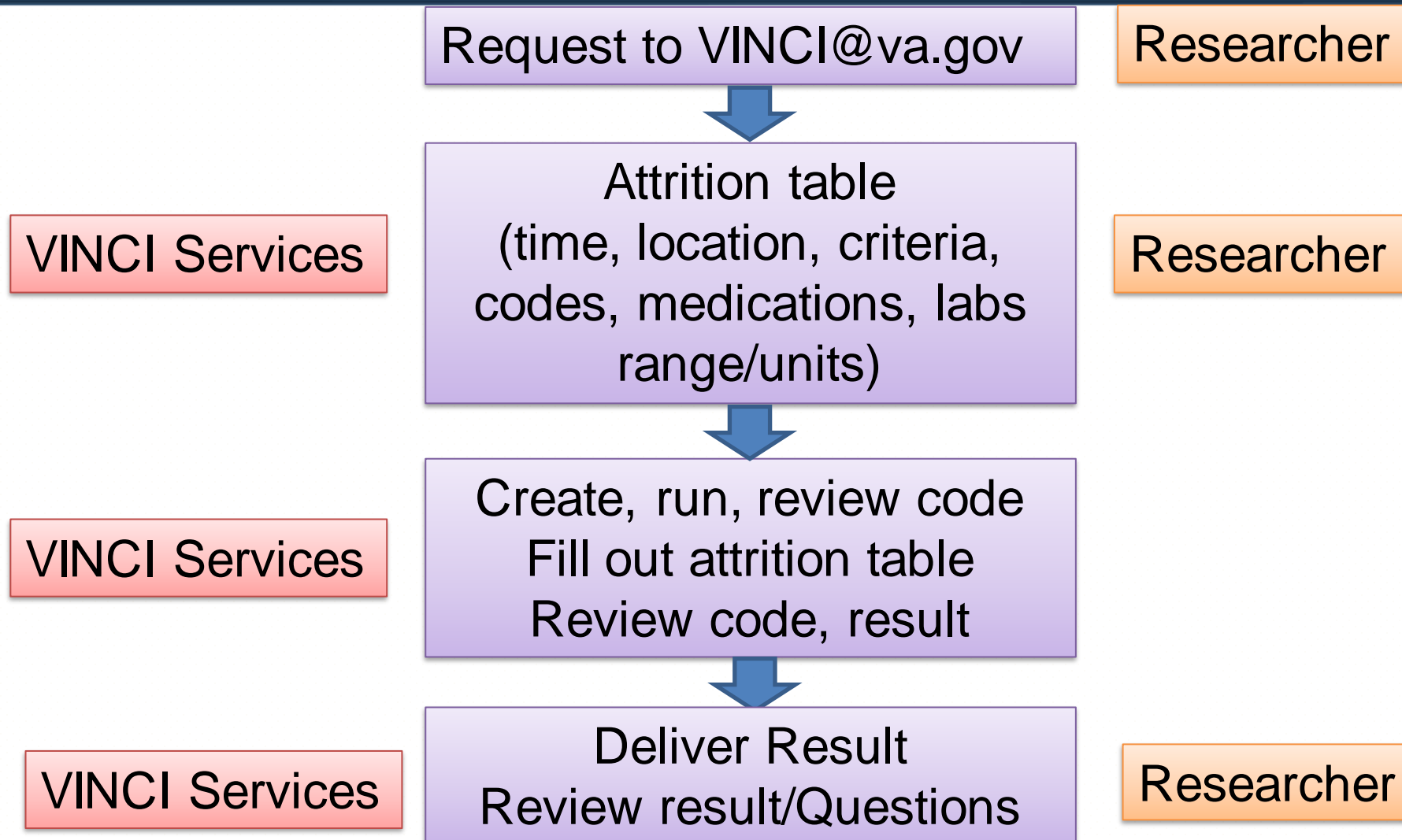
Researcher

Preparatory to Research _ PTR DART

Preparatory to research Can be conducted by research team **(**Feasibility project (cohort size and structure; result cannot be published)
- **<u>SQL skills</u>**
- DART Preparatory to Research Request Process

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

Preparatory to Research _ PTR DART

Preparatory to Research _ PTR DART

ⓘ Activity Information

REQUEST INFORMATION

Proposed Protocol Name *	title
Expected IRB Submission Date *	📅 01/25/2025

PTR data base and project folder will be archived after Expected IRB Submission Date

Participant page: **Team members need access to the data**

👤 Participants

PARTICIPANTS & LOCATIONS

Name	AD Alias	Location	Notifications	Data Access	CAPRI/JLV ❓ Application Account	Delete
Efimova, Olga V.	VHASLCEfimoO	(660) Salt Lake City HCS (Salt Lake City UT)	☑	☑	☐	🗑
🔍 Find People		🔍 508 Select a Location ▾	☐	☐	☐	Add

Important! Please select a Primary Location and a Principal Investigator for each location. ✕

Primary	Location	Principal Investigator
★	(660) Salt Lake City HCS (Salt Lake City UT)	✏ Efimova, Olga V.

Preparatory to Research _ PTR DART limitation

Data Sources

Data Storage
- Only VINCI
- Do not transfer data outside of the VA

No data sources:
- DoD-VA Infrastructure for Clinical Intelligence (DAVINCI)
- My HealtheVet Administrative Data
- National Precision Oncology Program (NPOP) Data base
- Traumatic Brain Injury Screening and Evaluation Data
- VA Surgical Quality Improvement Program (VASQIP)

Limited
- Geriatrics and Extended Care (GEC)

VIReC

Data Access

VINCI

Preparatory to Research _ PTR DART limitation

📄 Documents

Preparatory to Research Memorandum
Required for Production Domains, Text Integration Utility (TIU) Text Notes, VA Millennium

Real SSN Access Request
Required for Production Domains, Text Integration Utility (TIU) Text Notes, COVID-19: Shared Data Resource, VA
Corporate Data Warehouse, VA Millennium

[DART Preparatory to Research Request Process (va.gov)](#)

DART Preparatory to Research Request Process

🔊 Overview	● Submitting a Request	📖 Documents & Forms	📊 Request Metrics	📄 Resources
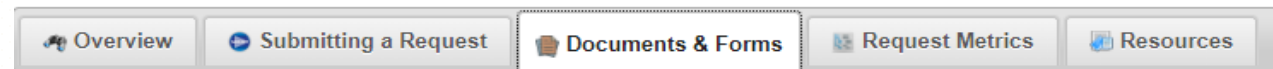
Documents & Forms

DART will generate a list of documents and forms that you are required to submit. Here is a list of documents and forms you may need. Note: Institutional Review Board (IRB) approval and waivers of HIPPA authorization are not required for PTR access to PHI data.

Important! Tips for Viewing & Downloading Forms

How to download and view forms.

a. Right click on the link to a form in the table below.

b. Select "Save link as..." and save form locally.

c. Open PDF forms in Acrobat Reader DC or Adobe Acrobat DC and select "Enable all features" to view content and fill out form.

Regulatory: Grant proposal/IRB/ R&D

Research projects
- Protocol
- IRB
- R&D
- **DART (**The Data Access Request Tracker)/ Request list of patients from VINCI Services for the prospective projects/ Request access for the data for retrospective project
http://vaww.vhadataportal.med.va.gov/DataAccess/DARTRequestProcess.aspx#SubmitRequest
- Forms for the Additional data sources

Preparatory to Research _VINCI for IRB

VINCI Central – Home va.gov

Preparatory to Research: IRB/ R&D

Required Information in Project Protocol

- VINCI description for IRB IRB Study How-To (va.gov)

> 3. **As part of your IRB package you are required to state where data will be stored for analysis. If you are planning to use VINCI for data storage and analysis we provide the following environment and security descriptions for use with IRB packages.
> - VINCI Description for IRBs
> - VINCI Information Security Description

- Real SSN/ Scrambled SSN should be requested (CAPRI/JLV, IVC data, USVETS, non-VINCI data sources)

- Storage location (VINCI, Local Server, other) https://vincicentral.vinci.med.va.gov/Shared%20Documents/Policies%20and%20Forms/VINCI_Information_Security_Description.pdf

- If targeted population using 7332 diagnosis (drug abuse, alcohol abuse, HIV, sickle cell anemia) the following statement should be included in IRB Protocol & HIPAA: The purpose of the data is to conduct scientific research and that no personnel involved in the study may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner. Snapshot-VA-Confidentiality-of-Sensitive-Records.pdf (networkforphl.org)

Preparatory to Research: IRB/ R&D

Required Information in Project Protocol

- If project will need **CAPRI/JLV access**, it should be described in the protocol/IRB protocol and HIPAA Waiver ("Access to patients records on national level will be conducting using CAPRI/JVL applications")

- If project required   cause of death analysis using **MDR data**, it should be described in IRB protocol in study procedure section Mortality Data (va.gov)

- If project required **Medicaid /Medicare analysis using CMS data**, it should be described in IRB protocol in study procedure section VA/CMS Home

- Inclusion/ exclusion criteria

- Waiver of HIPAA Authorization

Preparatory to Research: IRB/ R&D

Inclusion/exclusion criteria

- o Location (nationwide or some specific location
- o Time frame
- o Age/gender/other limitation
- o Cohort definition with justification
    - Diagnosis
    - Procedures
    - Lab test.
    - Medications
    - Notes
    - Military Service information
    - Other

Preparatory to Research: IRB/ R&D

Inclusion/exclusion criteria

Ethics Principles for Access to and Use of Veteran Data

- Principle 7: All parties are obligated to ensure data security, quality and integrity of Veteran data.

All parties who send, receive, or use Veteran data must ensure data security, quality and integrity. In other words, that the data remain secure; accurate; complete; and representative of the data quality, meaning, and integrity when it was received or accessed from VA. ==Access to data should be limited to the minimum amount needed to accomplish the stated purpose==, and should be terminated when no longer required. Data that are not necessary to accomplish the purpose for which it was obtained should not be retained longer than legally required. Transparency about breaches in data security, quality or integrity is also essential to promote trust and minimize impacts to Veterans.

Ethics Principles for Access to and Use of Veteran Data - DigitalVA

Preparatory to Research: Documents

[DART Research Request Process (va.gov)](#)

The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on the presence of the following elements:

1. An adequate plan to protect the identifiers from improper use and disclosure.
2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law (e.g., to satisfy records retention requirements).
3. Adequate written assurances that the PHI will not be reused or disclosed except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule.

Must be signed by the Chair or other designated voting member and include the requirements of the IRB identification, date of waiver approval and review procedure used (convened or expedited).

Preparatory to Research _ Team

Preparatory to research/ Research project: VINCI provides data in **SQL format** thus studies will need their own SQL analyst / data manager to extract, manipulate, and analyze their data. VINCI will not do this for you.

VINCI Training & Office Hour (va.gov) / SQL and CDW Bootcamp

CDW Training (sharepoint.com)

Millennium data consultation

Category:VINCI SOP - CIPHER VA WIKI

THANK YOU!
Questions?

CONTACT INFORMATION

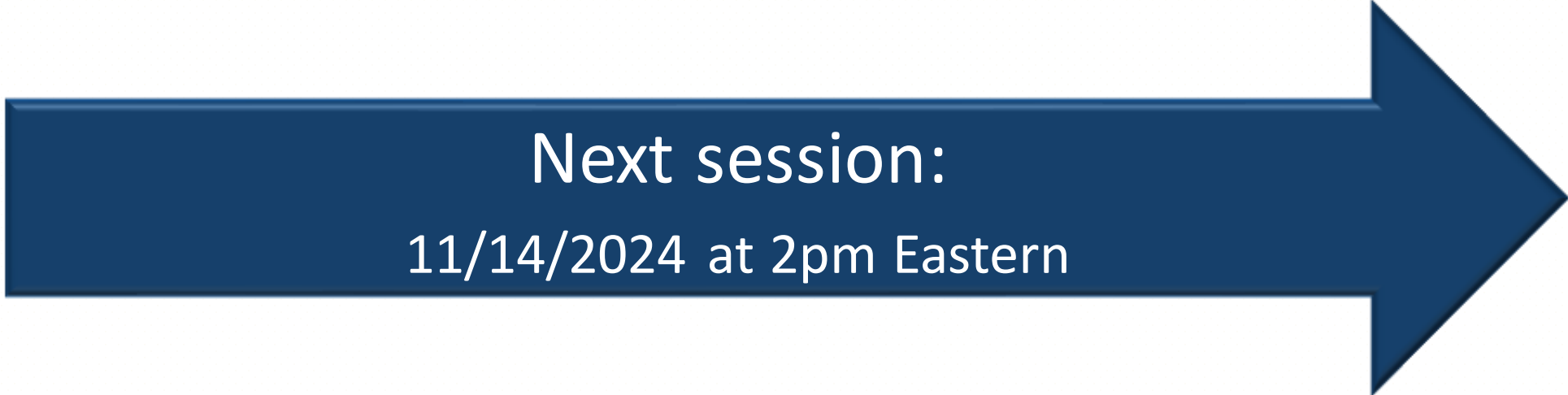- vinci@va.gov
- vinciservices@va.gov
- Olga.Efimova@va.gov

DATA ACCESS CYBERSEMINAR MINISERIES

Next session:
11/14/2024 at 2pm Eastern

VA Data Access Requirements for Operations

DATA ACCESS
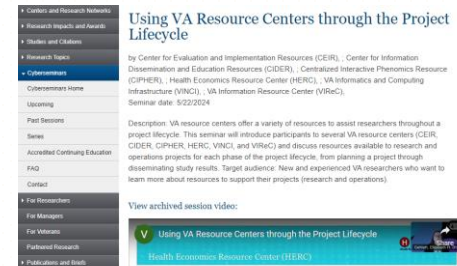# BONUS SLIDES

Resources for *VA Data Users*
Select image to visit page

VHA Data Portal (VA Intranet)

VA Information Resource Center (VIReC) (VA Intranet)

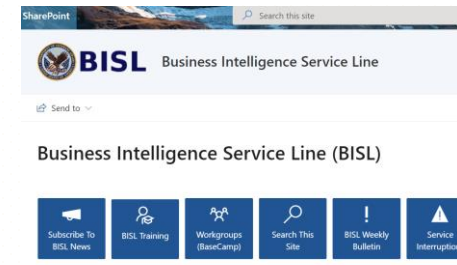Video: Using VA Resource Centers through the Project Lifecycle

VIReC Data Issues Brief

VA Millennium EHR Data Documentation (VA Intranet)

VA Informatics and Computing Infrastructure (VINCI) (VA Intranet)

BISL/CDW (VA Intranet)

Health Economics Resource Center (HERC) (VA Intranet)

VIReC Cyberseminar Series
Select series for more information

Database & Methods

Introduces VA data sources and information systems and their use in research.

Good Data Practices

Provides practical guidance on using data throughout the research project lifecycle.

Data Access

Reviews data access request processes and provides insight on regulatory requirements.

CMS Data

Focuses on CMS and USRDS data and methods for using these data in VA research.

Research & EHR Synergy

Helps VA researchers understand VA's transition to the Federal EHR and its impacts on VA data.

Partnered Research

Explores VA data use in evaluation, implementation, and research-operations partnerships.

Interested in presenting a Cyberseminar? Contact virecseminars@va.gov

Questions about using VA Data?

HSRData Listserv

- Community knowledge sharing
- ~1,900 VA data users
- Researchers, operations, data stewards, managers
- Subscribe by visiting
  vaww.virec.research.va.gov/Support/HSRData-L.htm (VA Intranet)

VIReC HelpDesk

- Individualized support
- Request Form:
  varedcap.rcp.vaec.va.gov/redcap/surveys/?s=KXMEN77LXK (VA Intranet)

VINCI HelpDesk

- Individualized support
- VINCIservices@va.gov