

# VA Office of Research & Development Available COVID-19 Research Resources and Infrastructure Fall 2021

COVID-19: Shared Data Resource - VA Phenomics Library

## VA COVID-19 Shared Data Resource

Contact: Kristine Lynch PhD <u>Kristine.Lynch@va.gov</u>

## National Surveillance Tool (NST)

- The VA National Surveillance Tool (VA-NST) is the authoritative data source for positive and negative COVID-19 cases
- Active data feeds that are provided to approved research databases and updated weekly include:
  - CaseDetail: identifies COVID-19 positive, negative, suspected, or pending patients, including potential hospitalization summary information
  - $\circ \quad {\sf CaseLabChem: identifies \ COVID-19 \ related \ lab \ tests}$
- <u>https://dvagov.sharepoint.com/sites/OITBISL/NST/SitePages/BISL\_NST-DOEx-Subscribers.aspx</u>

# CDW COVID-19 data

- Created and maintained by VINCI in collaboration with multiple VA researcher groups and operational partners
- Directly build from the NST data feeds and contains information on all patients who:
  - $\circ$  ~ received a COVID-19 laboratory test (positive or negative) within VA ~
  - $\circ$   $\,$  tested positive outside VA and information pertaining to the positive test was recorded in VA clinical notes
- Data elements/phenotypes derived from both structured and unstructured data related to:
  - Pre-existing conditions
  - Sociodemographic factors
  - Pharmacological and non-pharmacological interventions
  - Patient outcomes
  - Vaccinations
  - Curated dimension tables/data dictionaries
  - Community data
- Data are updated weekly

## CSP 2028 /EPIC<sup>3</sup>

Contact: Jonathan Sugimoto, PhD <u>Jonathan.Sugimoto@va.gov</u> or Study Coordinating Center <u>CSP2028CC@va.gov</u>

• CSP #2028 - <u>Ep</u>idemiology, <u>I</u>mmunology and <u>C</u>linical <u>C</u>haracteristics of <u>C</u>OVID-19

- Prospective cohort study enrolling individuals newly exposed to SARS-CoV-2 (and 1:1 matched unexposed) in outpatient setting, inpatients, and community living centers.
- Data: Biological specimens (blood, respiratory tract, stool, and residual clinical specimens), serial surveys related to baseline risk factors, SARS-CoV-2 vaccination, acute symptoms, and long-term COVID-19 outcomes, as well as EHR records
- Total currently enrolled: 1392/ Target: 1696
- Collaboratory with a similarly designed study conducted by the DoD
- The primary objective of this study is to describe the course of SARS-CoV-2 infection and symptomatic COVID-19 disease in Veteran VHA who are prospectively followed for two years. The study aims to investigate determinants of infection, disease, and the immune response among enrolled Veterans, as well as the effectiveness of treatments and vaccines against SARS-CoV-2/COVID-19. A key contribution of this study is to establish research repositories for clinical and laboratory data, a related research specimen repository, and a participant registry to support future studies of COVID-19 and other health conditions. The study's longer-term goal is to provide the lessons learned from this COVID-19 pandemic to better anticipate and manage pandemics in the future for VHA and the general population.
- https://www.seattle.eric.research.va.gov/research/CSP-2028-EPIC3/home.asp

# <u>COVID-19</u> Observational <u>Research</u> Collaboratory (CORC)

Contact: George Ioannou MD, MS George.Ioannou@va.gov

- National three-year retro/prospective cohort study of VA inpatients and outpatients diagnosed with COVID, compared to matched inpatient/outpatient controls.
- Data: EHR data on outcomes and risk factors; surveys for assessment of long-term symptoms.
- <a href="https://www.hsrd.research.va.gov/covid-19/">https://www.hsrd.research.va.gov/covid-19/</a>
- <u>COVID-19 Observational Research Collaboratory (CORC) VA Phenomics Library</u>

# Coverage and Effectiveness of mRNA COVID-19 Vaccines among Veterans (PI Yinong Young-Xu, White River Junction VAMC)

Contact: Yinong Young-Xu PhD <u>Yinong.Young-Xu@va.gov</u>

- National negative-case-control study involving all cases with PCR-confirmed COVID 19 and PCRnegative controls.
- Objective: To describe the scope of the mRNA vaccination rollout among the diverse U.S. Veterans population, and to study the mRNA COVID-19 vaccine effectiveness (VE) against infection, symptomatic disease, hospitalization, and death.
- https://www.medrxiv.org/content/10.1101/2021.06.14.21258906v3.full.pdf

#### Million Veteran Program (MVP)

Contact: MVPLOI@va.gov

• National repository of genomic and health data on over 850,000 Veterans, including 40,000 SARS-CoV-2 positive Veterans.

- Data: genotype data; EHR data; baseline and lifestyle surveys, and 2020 COVID-19 survey to MVP enrollees to assess COVID infection and health impacts as well as behavior and well-being impacts.
- <u>https://vaww.genisis.med.va.gov/genhub</u> (Register for an account in GenHub to view aggregate data in the MVP cohort)
- www.mvp.va.gov for more information about MVP

#### **CDC and VA SUPERNOVA**

Contact: Vince Marconi MD vcmarco@emory.edu

- CDC's program with projects at the VA: The Surveillance Platform for Enteric and Respiratory Infectious Organisms
- Project 1: Network of five Veterans Affairs Medical Centers (VAMCs) in the United States that conduct active and passive surveillance for acute gastroenteritis, with laboratory-confirmed testing of various pathogens, including norovirus & SARS-CoV-2. SUPERNOVA is an endemic disease surveillance system that provides data to estimate the prevalence and incidence of norovirus in adults. Ongoing surveillance using this platform will allow for characterization of the pathogen distribution and serologic response over time.
- Project 2: Established a data team from the VA to form the SUPERNOVA-VA project to look at the use of electronic system to extract information from patients' charts. Validation is in progress. If successful, the electronic method will be available to all VA stations. The data team consists of Vince Marconi, Mark Holodniy, Saiju Pyarajan, Scott DuVall, and Yinong Young-Xu.
- https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e3.htm#:~:text=What%20is%20added%2 0by%20this,1.617

## VA Sequencing Collaborations United for Research and Epidemiology (VA SeqCURE)

Contact: Jane Battles PhD Jane.Battles@va.gov

- Network of five VA sites with initial funding by the American Rescue Plan Act of 2021: Cleveland VA, Durham VA, Iowa City VA, Boise VA, and Temple VA
- Objective is to generate sequencing data to complement the variant sequencing efforts at VA clinical labs (VA SEQFORCE) for public health surveillance. Various research-protocol based and public health surveillance sequencing projects such as vaccine effectiveness in SARS-CoV-2, samples from State Public Health agencies, and analysis on other emerging pathogens such as antimicrobial resistance organisms.
- Data of each project will be available in the future.

## VA Science and Health Initiative to Combat Infectious and Life-Threatening Diseases (VA SHIELD)

Contact: Holly Krull, PhD <u>holly.krull@va.gov</u>

• A comprehensive, secure biorepository of specimens and associated data related to COVID-19 and other emerging diseases. These specimens and data are available to authorized VA investigators—and, under certain circumstances, to their external collaborators—to advance scientific understanding in support of developing diagnostic, therapeutic, and preventative strategies for use in clinical care.

https://www.research.va.gov/programs/shield/default.cfm

#### **VA CURES Program**

Contact: Terri Gleason PhD theresa.gleason@va.gov

- VA CoronavirUs Research & Efficacy Studies
- Initially established as a clinical trial master protocol framework built to support and maximize the efficiency of COVID-19 clinical trials, VA CURES now serves as a partnering network of trials and VA trial sites. Capabilities include:
  - VA site network for partnership, e.g., ACTIV trials including 4A
  - Develop master protocols for adaptive randomized clinical trials (RCTs)
  - o Develop policies for publications, ancillary studies and biospecimen collection
- https://www.research.va.gov/services/csrd/va\_cures/default.cfm

#### **ACTIV** Studies

Contact: Victoria Davey PhD, MPH, RN victoria.davey@va.gov

- Accelerating COVID-19 Therapeutic Interventions and Vaccines
- Coordinated by the Foundation for the National Institutes of Health (FNIH), ACTIV brings NIH together with its sibling agencies in the Department of Health and Human Services, including the Biomedical Advanced Research and Development Authority (BARDA), Centers for Disease Control and Prevention (CDC), and the U.S. Food and Drug Administration (FDA); other government agencies including the Department of Defense (DOD) and Department of Veterans Affairs (VA); The Operation (formerly known as Operation Warp Speed); the European Medicines Agency (EMA); and representatives from academia, philanthropic organizations, and numerous biopharmaceutical companies. ACTIV is organized into 3 areas: pre-clinical, therapeutics, and prevention. VA is contributing to preclinical activities in Tracking Resistance and Coronavirus Evolution (TRACE) identifying emerging viral mutants and in four ACTIV clinical trials: ACTIV-3A (TICO), ACTIV-3b (TESICO), and ACTIV-3c (VATICO), and ACTIV-4a.
- <u>https://www.nih.gov/research-training/medical-research-initiatives/activ/tracking-resistance-coronavirus-evolution-trace</u>
- https://www.nih.gov/research-training/medical-research-initiatives/activ
- ACTIV-3: Therapeutics for Inpatients With COVID-19 (TICO)
- Vaccination for Recovered Inpatients With COVID-19 (VATICO)
- ACTIV-3b: Therapeutics for Severely III Inpatients With COVID-19 (TESICO)
- <a href="https://clinicaltrials.gov/ct2/show/NCT04505774?term=ACTIV-4&draw=2&rank=1">https://clinicaltrials.gov/ct2/show/NCT04505774?term=ACTIV-4&draw=2&rank=1</a>