

# CRS Explorer

## HIV/AIDS Network Clinical Research Sites

### Application User Guide



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# SECTION

# A

Purpose





The purpose of this website is to provide information describing the global clinical research infrastructure available to conduct NIAID HIV/AIDS multi-center clinical studies.

The website displays information on research partners, their potential participant populations, as well as their basic laboratory and pharmacy capability. It is intended to assist NIAID Clinical Trials Network staff in accessing potential resources for on-going and/or future Network studies. It is for informational purposes only.

## SECTION

# B

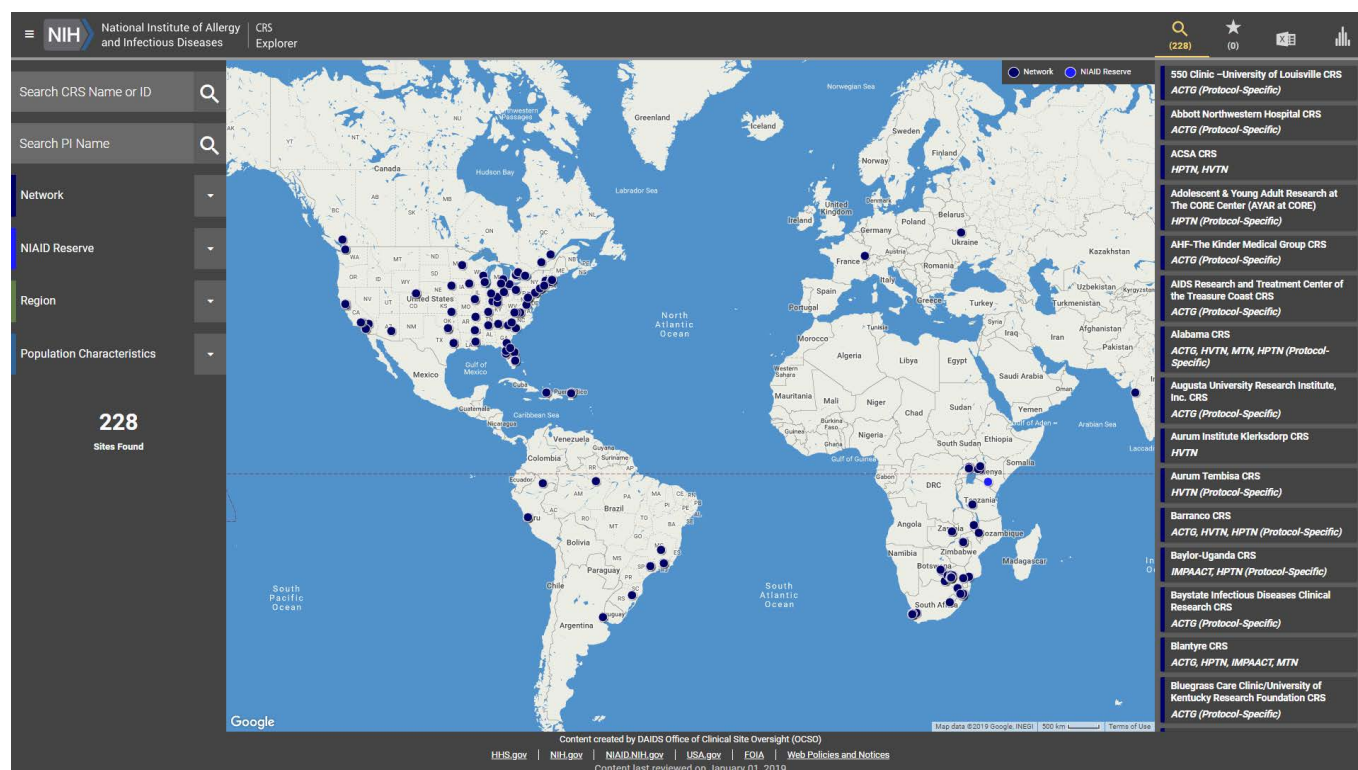


## Helpful Hints

# Helpful Hints



Upon entering the website, the map will show all NIAID HIV/AIDS sites and their locations around the world.



Use the [Left Navigation Menu](#) to filter the collection of sites and then use the [Right Navigation Menu](#) to see your *Search Results* [magnifying glass icon]. The user can select a subset of sites to add to your *Favorites List* [Star Icon], *Export to Excel* [Excel Icon] or *Graph* [Bar Graph Icon].

In the [CRS Profile View](#), [Laboratory View](#), [Pharmacy View](#) click the *Question Mark Icon* to see a brief explanation of specific field descriptions; click the *Home Icon* on the **Right Navigation Menu** to return to the [Home Page](#); and, click the *Globe Icon* to return to the [Main Map](#).

# SECTION

# C



## User Manual

## I. Home Page



### 1.1 Navigation Icons



#### **Explore**

This icon will send the user to the **Main Page**



#### **About**

Introduces the website and provides a brief background



#### **Tutorial**

Displays a video walk-through of how to use the website, as well as an Application User Guide (available as a PDF)



#### **Acronyms & Glossary**

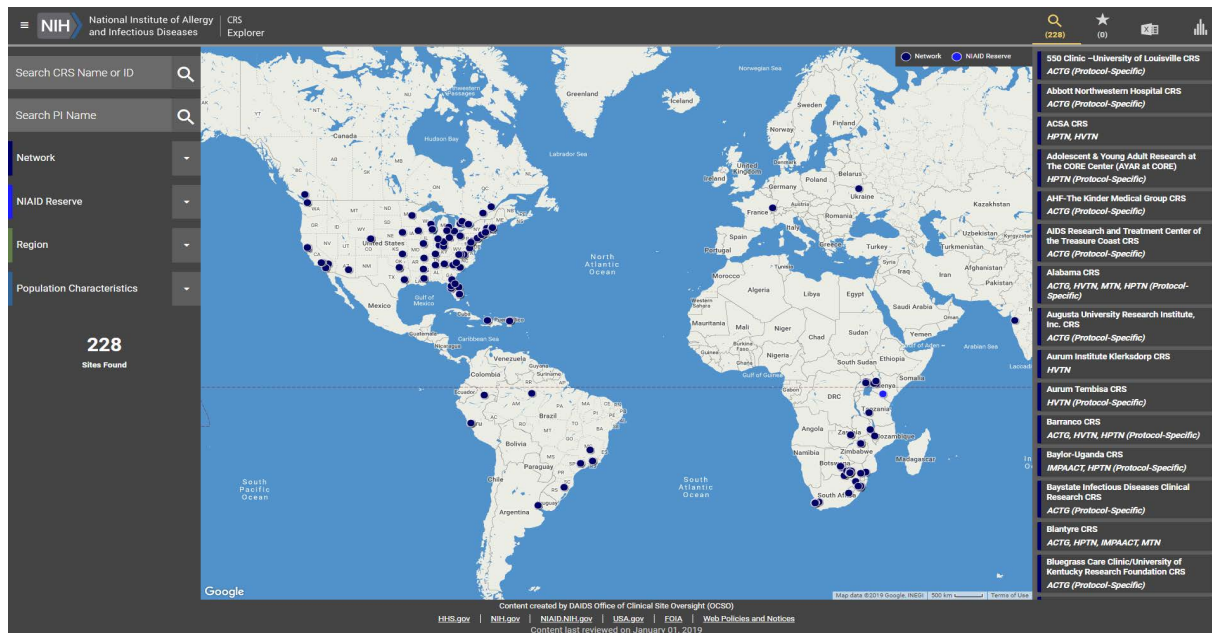
List of key terms and acronyms with their definitions



#### **Contact Us**

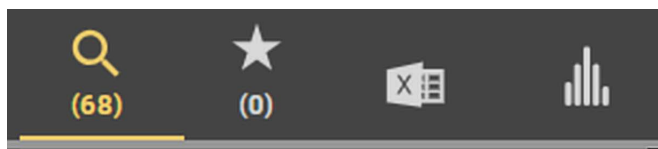
General Contact Info about website and DIAIDS

## II. Main Map



### 2.1 Map Elements

The **Main Map** will display markers for all CRSs in the NIAID HIV/AIDS Clinical Research Network. The default view will display all the available sites in the portfolio.



The **Main Map** also has the capability to display the user's *Search Results* [Magnifying Glass Icon] as a list of sites on the right side, by clicking the **Magnifying Glass Icon** from the **Right Navigation Menu**. When selected, the Magnifying Glass Icon will turn yellow.



Alternatively, sites added to the user's *Favorites List* may be displayed by clicking on the Star Icon on the **Right Navigation Menu**. The Star Icon will turn yellow when selected.



[“Network”](#) sites will be identified by a red circular marker on the **Main Map**.

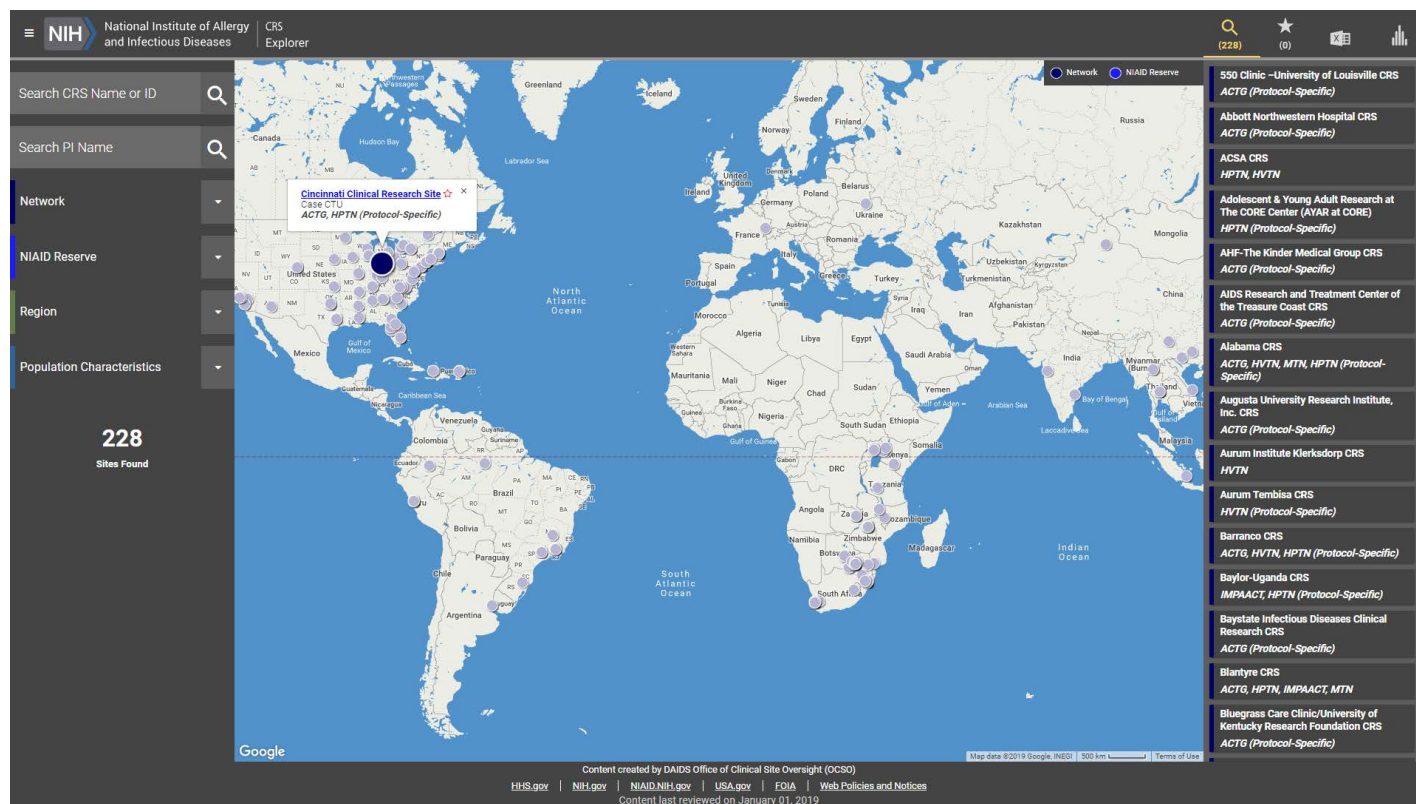


[“NIAID Reserve”](#) sites by a pink circular marker on the **Main Map**.



## 2.2 Filter Site Markers

Use the category options on the **Left Navigation** to filter the sites displayed on the **Main Map**.



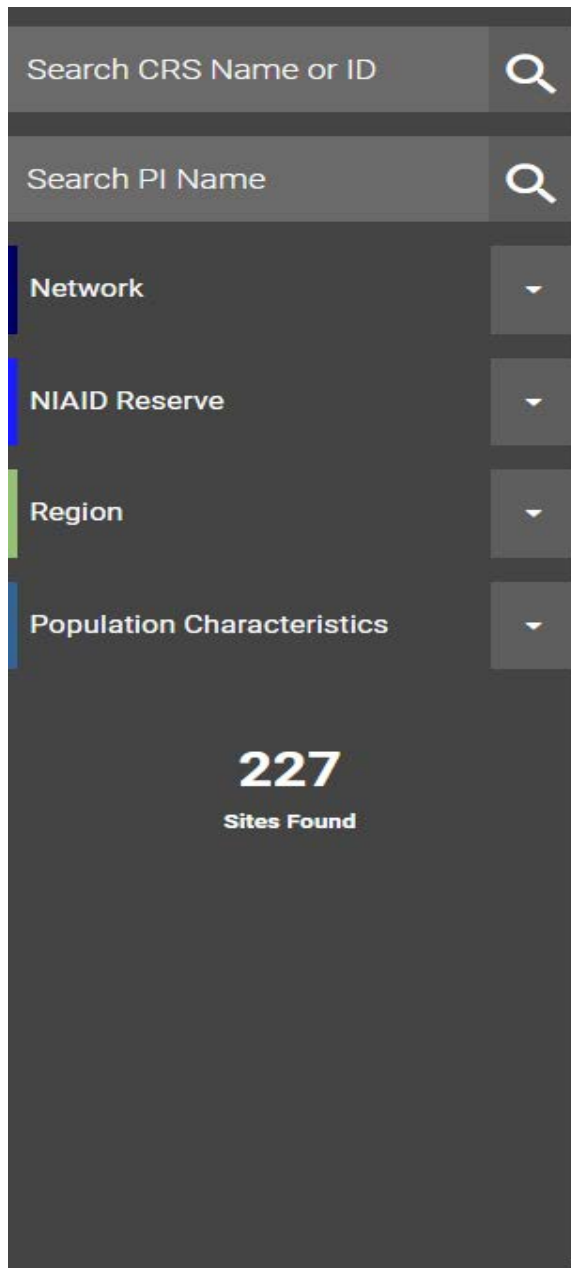
User can click on **Map Marker** to see the site information card with CRS name, CTU name and Network Affiliation(s):



# III. Left Navigation Menu

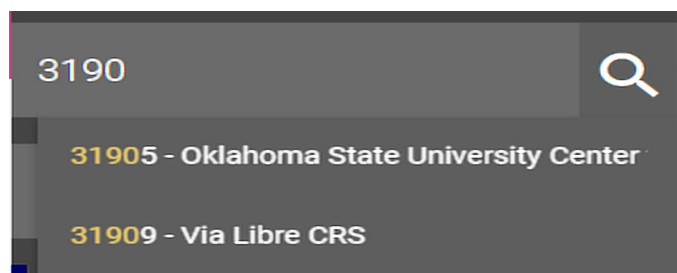
## 3.1 Filter Criteria

The **Left Navigation** contains categorized filters to help narrow the user's *Search Results*. Sites can be filtered by six main criteria. Each criteria option can accommodate multiple filter selections.



### Clinical Research Site (CRS)

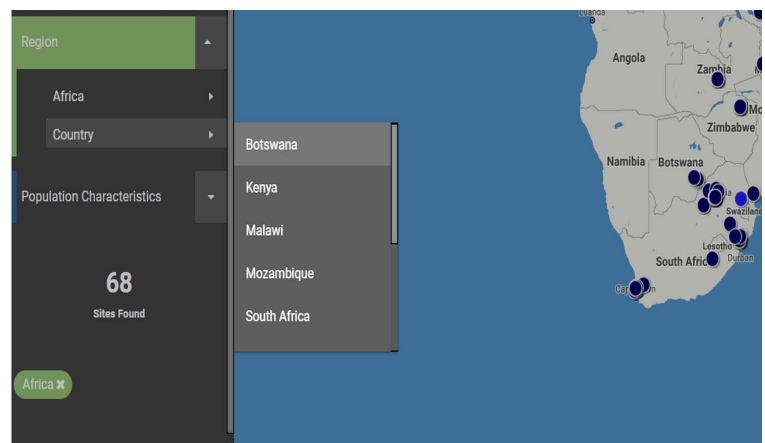
The user can search by typing a CRS name or CRS ID number. A drop down menu will auto-populate based on user input.



### Region

The user can search available regions by:

- Continent
- Country
- State

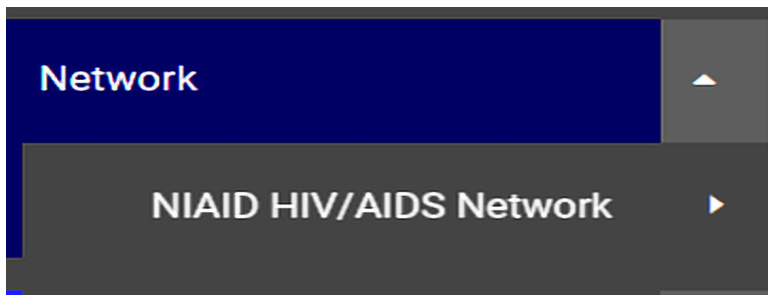




## Population Characteristics

The user can search available participant criteria.

- Gender
- Age
- Race/Ethnicity
- Risk Factor
- Disease/Condition



## Network

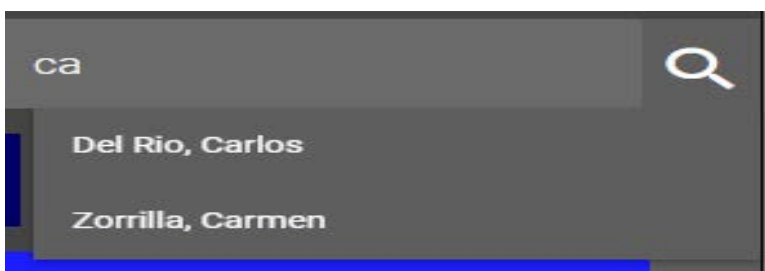
The user can search by NIAID HIV/AIDS Clinical Trials Networks:

- ACTG
- HPTN
- HVTN
- MTN
- IMPAACT
- ACTG (Protocol Specific)
- HPTN (Protocol Specific)
- HVTN (Protocol Specific)
- MTN (Protocol Specific)
- IMPAACT (Protocol Specific)
- Protocol Specific Only



## NIAID Reserve

The user can search NIAID HIV/AIDS Clinical Trials Network Reserve sites

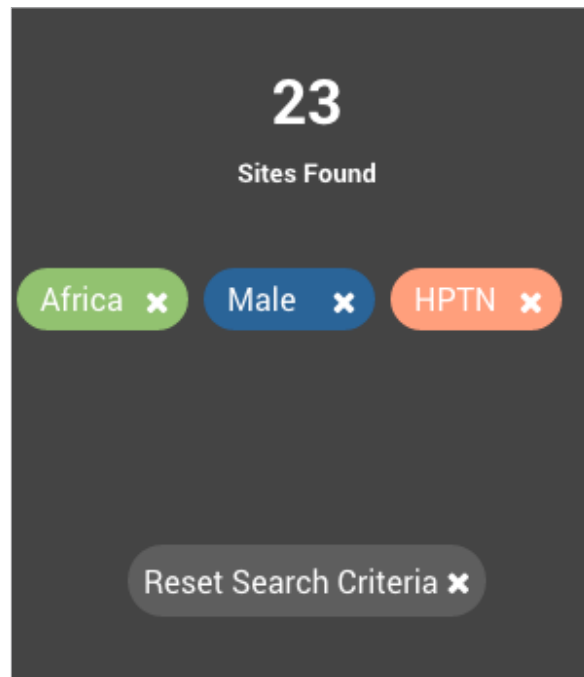


## Principal Investigator (PI)

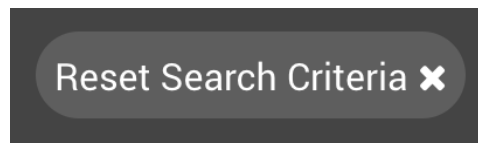
The user can search by typing the name of the Principal Investigator. A drop down menu will auto-populate based on user input.

### 3.2 Adjust Criteria

The selected criteria are identified as *Chip(s)* [*Oblong Oval Icon(s)*] and are located at the bottom of the **Left Navigation Menu** and beneath the “CRS” and “PI” filters. Filters shown on these *Chip(s)* may be removed from search criteria individually by clicking the X on the right side of each *Chip*.



All filters may be reset by clicking the “Reset Search Criteria” button, which is located at the bottom of the **Left Navigation Menu**.

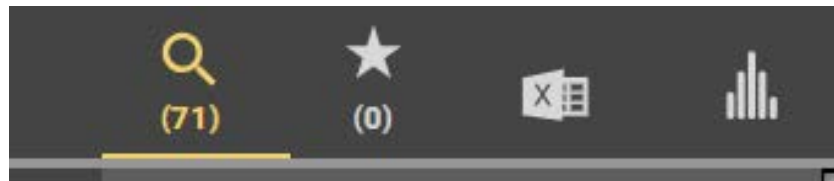


At the top of the **Left Navigation Menu** the user will find the *Hamburger Button* (see below) for collapsing the **Left Navigation Menu** which will give the user a bigger view of the map. Clicking on the **Title** to return the user to the **Home Page**.



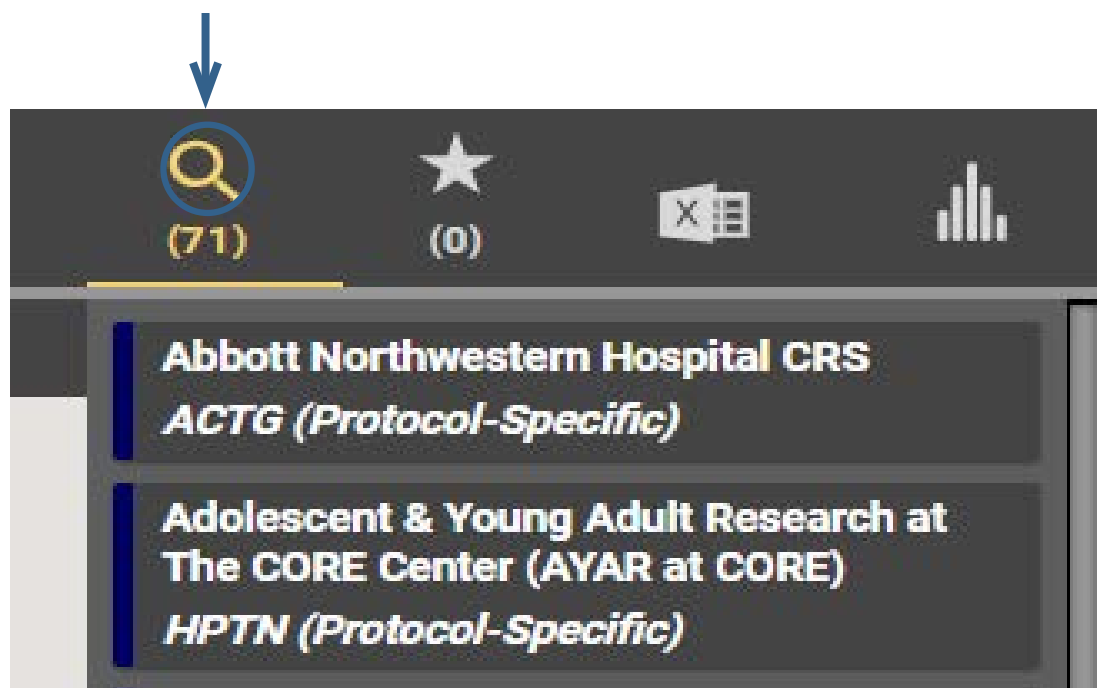
## IV. Right Navigation Menu

The **Right Navigation Menu** gives the user various ways to sort and view their search criteria and result.



### 4.1 Search Result Icon

Clicking the *Magnifying Glass Icon* will turn the icon yellow and display a list of Search Results, under the **Right Navigation Menu**. To hide this list, click on the *Magnifying Glass Icon*, which will turn back to white and the site-cards will be hidden.



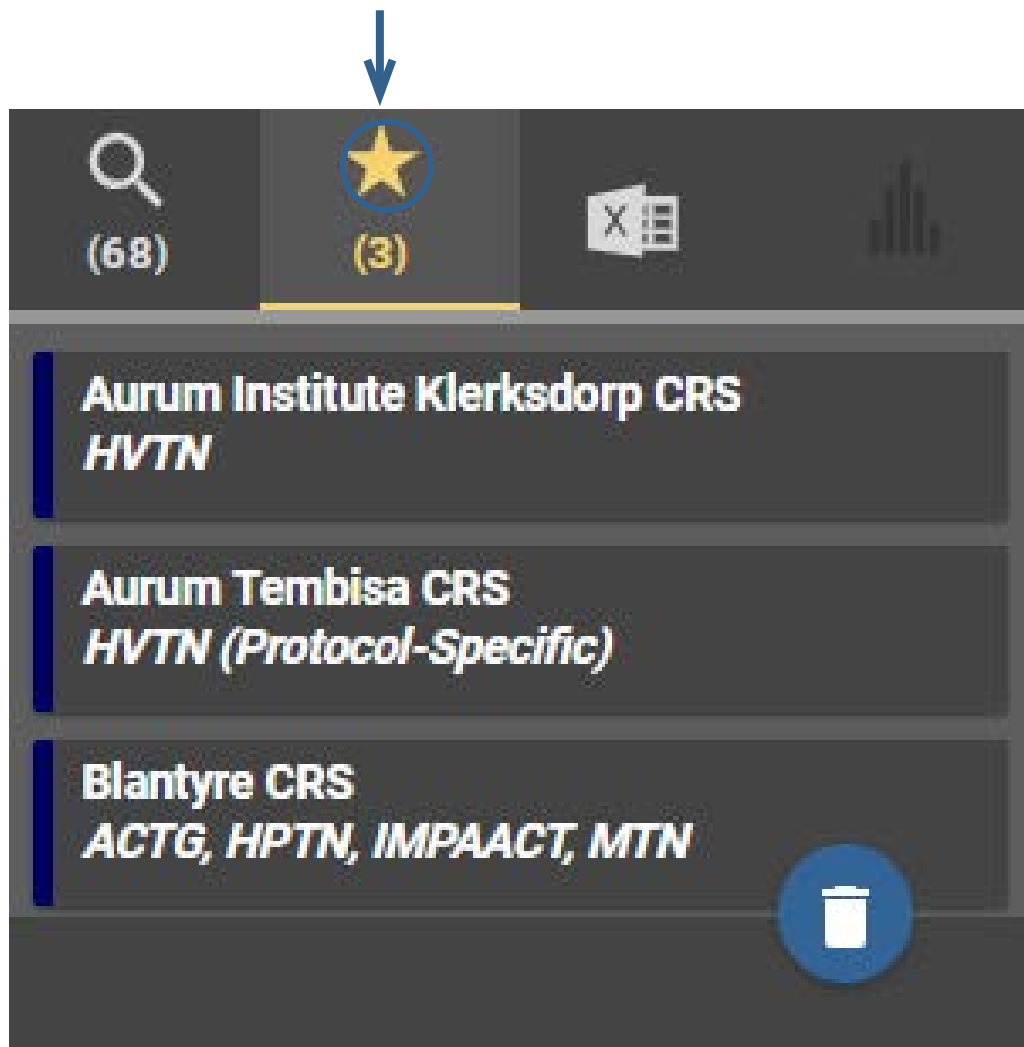
Hovering over a site-card will result in the **Main Map** automatically adjusting to focus on that site location.

## 4.2 Favorites List

The user may also add a site(s) to the *Favorites List* in two ways:

1. Click on a *Star Icon* next to the site name as it appears on the map.
2. Using the mouse, hover over a site card that appears in the *Search Results List* and click on the *Star Icon* to the left of the CRS name.

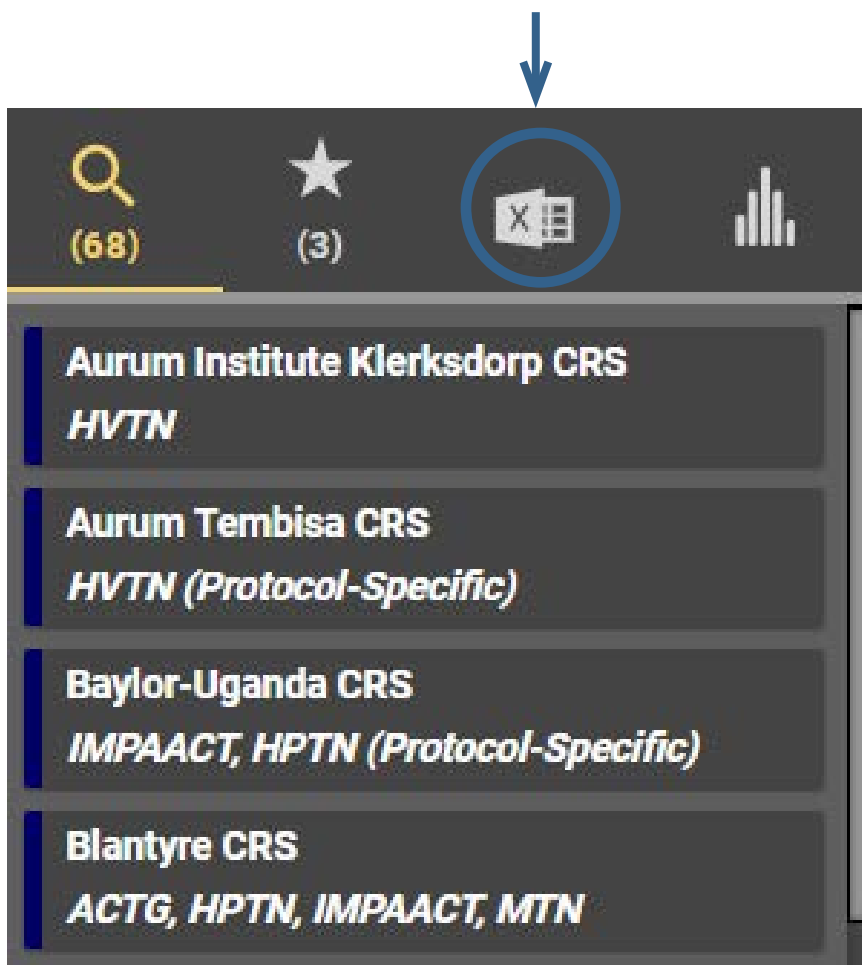
The *Favorites List* can be accessed by clicking on the *Star Icon* located to the **Right Navigation**.



The *Blue Trash Can Icon* will clear the *Favorites List* [Star Icon].

## 4.3 Export Excel Report

The user may export either the *Search Results* [Magnifying Glass Icon] or *Favorites List* [Star Icon] into an Excel file by clicking the *Export to Excel* button [Excel Logo Icon] located to the right of the *Favorites List* [Star Icon] (exported data will be from the selected list with the corresponding yellow icon. For example, the Excel export below will be for Search Results.)



Open download using Excel for further use:

	A	B	C	D	E	F	G
	CRS Continent	CRS Country	CRS City	CRS Name	CRS Site Number	CRS Leader	CTU PI
3	Africa	Botswana	Gaborone	Gaborone CRS	12701	Mashoto, Gerolwe	Esau, Myron (Moi), Lockman, Shahin
4	Africa	Botswana	Gaborone	Center for Disease Control (CDC) Botswana TB/HIV Res n/a		Shepherd, James	Del Rio, Carlos; Lonnax, Jeffrey; Mulligan, Mark
5	Africa	Botswana	Molepolole	Molepolole CRS	12702	Omoze-Garhe, Ayotunde	Esau, Myron (Moi), Lockman, Shahin
6	Africa	Kenya	Eldoret	Moi University Clinical Research Center (MUCRC) CRS	12501	Sika, Abraham	Michael, Nelson
7	Africa	Kenya	Kenya	Kenya Medical Research Institute/Waiter Reed Project	12501	Sawa, Fredrick	Michael, Nelson
8	Africa	Kenya	Kisumu	KISUMU CRS	31490	Schnabel, David	Del Rio, Carlos; Lonnax, Jeffrey; Mulligan, Mark
9	Africa	Malawi	Blantyre	Blantyre CRS	30301	Dadashai, Sufia	Taha, Taha E
10	Africa	Malawi	Lilongwe	Malawi CRS	12001	Cheniko, Lameck	Eron, Joseph; Hossainpour, Mine
11	Africa	Mozambique	Maputo	Polana Centro Health Research and Training Center (C	31795	Jani, Esh	Michael, Nelson
12	Africa	South Africa	Cape Town	Desmond Tutu TB Centre CRS	31744	Boysen, Nkula	n/a
13	Africa	South Africa	Cape Town	University of Cape Town Lung Institute (UCTLI) CRS	31792	Dawson, Rodney	Belker, Linda-Gail
14	Africa	South Africa	Cape Town	Task Applied Science (TAS) CRS	31718	Diazon, Andreas	Cotton, Mark
15	Africa	South Africa	Cape Town	Desmond Tutu TB Centre - Stellenbosch University (DT	31790	Hoopling, Arnoldo	Cotton, Mark
16	Africa	South Africa	Cape Town	Meyikotho CRS / (CIRM UCT)	31941	Mekjes, Greemo	Belker, Linda-Gail
17	Africa	South Africa	Cape Town	Emanandeni CRS	30345	Nair, Gonsagrio	Belker, Linda-Gail
18	Africa	South Africa	Cape Town	Groote Schuur HIV CRS	31708	Orrill, Catherine	Belker, Linda-Gail
19	Africa	South Africa	Chatsworth	Chatsworth CRS	30302	Jochheim, Ntshhe	Ramsey, Gita
20	Africa	South Africa	Durban	Durban International Clinical Research Site CRS	11201	Lufesi, Umash	Berman, Constance
21	Africa	South Africa	Durban	United CRS	30300	Moodley, Olayandire	Abdool Karim, Quamasha
22	Africa	South Africa	Durban	eThekweni CRS	31422	Pedapatchi, Moni	Abdool Karim, Quamasha
23	Africa	South Africa	Durban	Botha's Hill CRS	31445	Swa, Samantha	Ramsey, Gita
24	Africa	South Africa	Isipingo Reef	Isipingo CRS	31635	Wondor, Kubeishin	Ramsey, Gita
25	Africa	South Africa	Johannesburg	White Helen Joseph Hospital CRS (White HJH CRS)	11101	Bedel-Fawson, Sherlize	Ross, Helen; Sennis, Jan
26	Africa	South Africa	Johannesburg	Soweto CRS	31029	Connadie, Francosca	Ross, Helen; Sennis, Jan
27	Africa	South Africa	Johannesburg	Ward 21 CRS	31955	Dolany-Morethwa, Sinead	Ross, Helen; Sennis, Jan
28	Africa	South Africa	Johannesburg	White Reproductive Health and HIV Institute CRS (WHI	31639	Dolany-Morethwa, Sinead	Ross, Helen; Sennis, Jan
29	Africa	South Africa	Johannesburg	White RH Shandani Research Centre CRS	30351	Furber, Leo	Ross, Helen; Sennis, Jan
30	Africa	South Africa	Johannesburg	Kaptein Swetse CRS	31028	Hunt, Nicole	Gray, Shmuel; Michale, Dorcas; Panchia, Ravindra

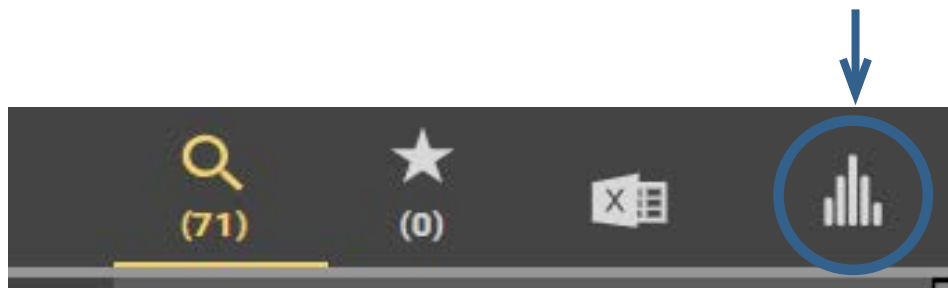


## 4.4 Globe & Graph Icons

The **Globe Icon** will appear anytime the user visits the **Data Visualization** or the **CRS Profile View** and will return the user to the **Main Map**.



Clicking the **Graph Icon** will create a graph of the selected list of sites.



## 4.5 Home Icon

Clicking the **NIH Logo Icon** at the far left end of the **Navigation Bar** at any point will return the user to the **Home Page**.

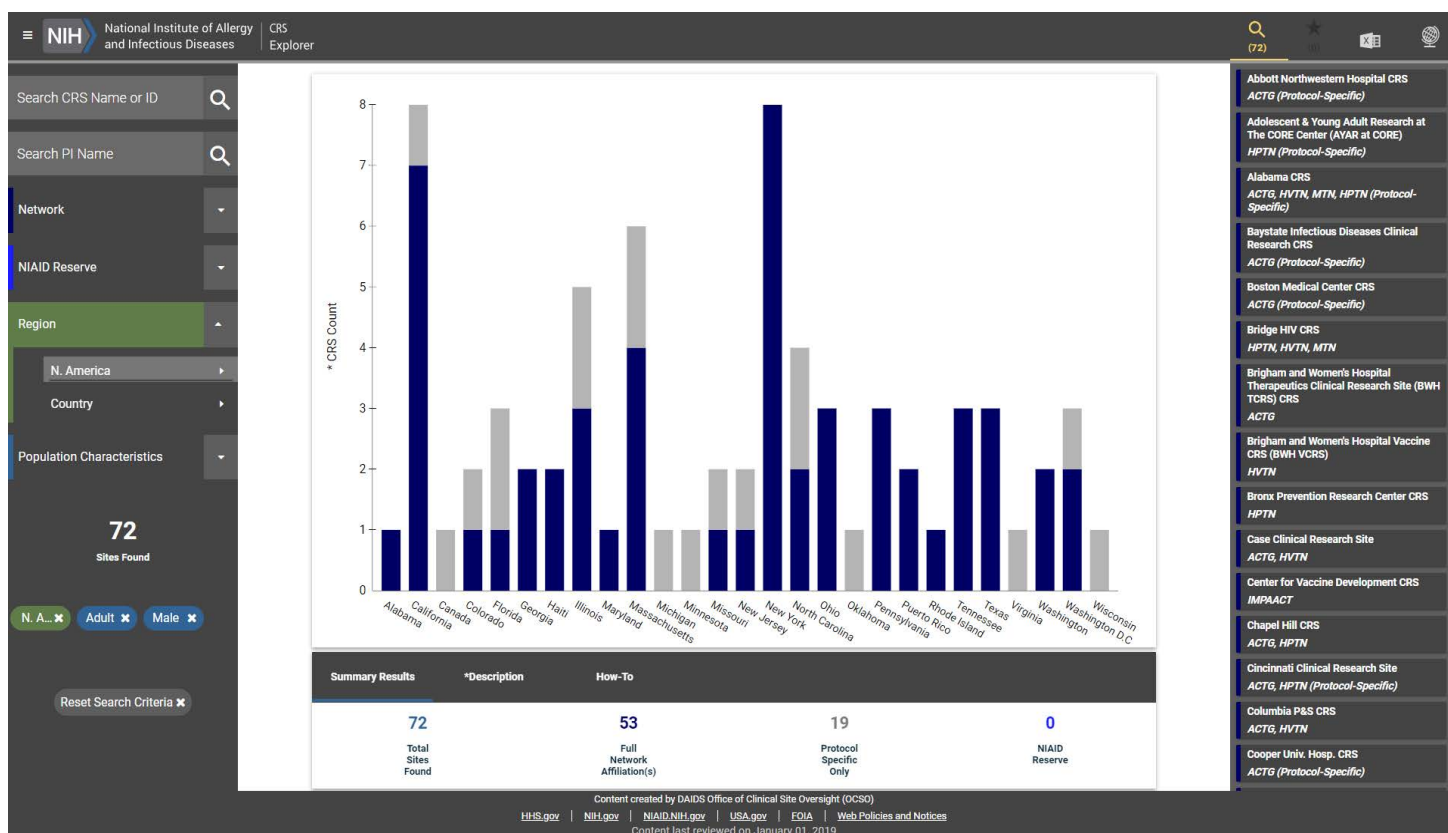




# V. Data Visualization

Clicking on the **Graph Icon** will provide a graphical depiction of the data in the user's **Search Results**. This graph displays information by:

- Total Sites Found
- Full Network Affiliation(s)
- Protocol Specific Only
- NIAID Reserve



The **Data Visualization** includes a description and how-to information beneath the graph.

Clicking the NIH Logo Icon at the far left end of the Navigation Bar at any point will return the user to the Home Page.



## VI. CRS Profile View

To see a **Profile View** click on a site – via **Main Map** or select a site-card from the **Right Navigation Menu**. The **CRS Profile View** displays the NIAID HIV/AIDS Clinical Research Network Site information as reported by the site:

### NIAID Networks

- Network Affiliation(s)
- Site Status
- NIAID Reserve
- Protocol Specific Activity

### CRS Information

- CRS Leader
- CRS Coordinator
- Clinic Address
- CTU Name
- Contact PI
- Multi-PI's
- Program Officer
- CRSs Associated with CTU

### CRS Regulatory Requirements

- National Regulatory Authority(ies)
- Local Institutional Review Boards and Ethics Committee Names
- Other Institutional Review Boards/ Ethics Committee Names
- Institutional Biosafety Committee
- Clinical Trials Insurance Required
- Languages (spoken at the site)

**NIH** National Institute of Allergy and Infectious Diseases | CRS Explorer

**Profile**

**Pharmacy**

**Laboratory**

**Population Characteristics**

Any changes to information contained in this CRS profile must be requested through the Program Officer.

**31858 - 550 Clinic - University of Louisville CRS**

**NIAID Networks**

Network Affiliation(s): ACTG (Protocol-Specific)

Site Status: Active

**Clinical Research Site (CRS) Information**

CRS Leader: Ramirez, Julio

CRS Coordinator: Gautam, Sabina

Clinic Address: 501 E. Broadway Suite 210  
Louisville, Kentucky 40202  
United States

Program Officer: Guerra, Isabel

**550 Clinic - University of Louisville CRS**

ACTG (Protocol-Specific)

Abbott Northwestern Hospital CRS

ACTG (Protocol-Specific)

ACSA CRS

HPTN, HVTN

Adolescent & Young Adult Research at The CORE Center (AYAR at CORE)

HPTN (Protocol-Specific)

AHF-The Kinder Medical Group CRS

ACTG (Protocol-Specific)

AIDS Research and Treatment Center of the Treasure Coast CRS

ACTG (Protocol-Specific)

Alabama CRS

ACTG, HVTN, MTN, HPTN (Protocol-Specific)

Augusta University Research Institute, Inc. CRS

ACTG (Protocol-Specific)

Aurum Institute Klerkadorp CRS

HVTN

Aurum Tembisa CRS

HVTN (Protocol-Specific)

Barranco CRS

ACTG, HVTN, HPTN (Protocol-Specific)

Baylor-Uganda CRS

IMPACT, HPTN (Protocol-Specific)

Baystate Infectious Diseases Clinical Research CRS

ACTG (Protocol-Specific)

Blantyre CRS

ACTG, HPTN, IMPACT, MTN

Bluegrass Care Clinic/University of Kentucky Research Foundation CRS

ACTG (Protocol-Specific)

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Content last reviewed on January 01, 2019

The **CRS Profile View** displays a zoomed in **Profile Map-View** of the CRS location as well.



The **Email Icon** located next to the Program Officer's name will open up a blank email to that Program Officer.



The **Drop Down Icon** for CRSs associated with CTU will display other Clinical Research Sites associated with that Clinical Trial Unit.

# VII. Laboratory View

By clicking “Laboratory” on the **Left Navigation**, while in The **CRS Profile View**, the user will see laboratory information for the selected CRS as reported by the site. The Laboratory View includes the following:

## NIAID Networks

- Affiliation(s)
- Name
- Address
- Related CRS(s)
- Network Affiliation
- Accreditation
- Quality Assurance

## Tests Performed

- CD4
- Cytology
- Metabolic Tests
- Pharmacology
- TB
- Viable PBMC Freezing
- Chemistry
- Hematology
- Immunology
- Microbiology
- Serology
- Toxicology
- Virology

The screenshot displays the NIH CRS Explorer interface. The left sidebar shows the navigation menu with 'Laboratory' selected. The main content area is titled '107 - Brigham and Women's Hospital Therapeutics Clinical Research Site (BWH TCRS) CRS'. It features a 'Laboratory Information' section with fields for Name, Address, Network Affiliation, and Accreditation. Below this is a 'Tests Performed' section with a grid of test categories. A map of the Boston area is shown, with a green dot and beaker icon indicating the laboratory location. The right sidebar lists other CRS sites.

**107 - Brigham and Women's Hospital Therapeutics Clinical Research Site (BWH TCRS) CRS**

Lab 1 Lab 2 Lab 3 Lab 4 Lab 5

**Laboratory Information**

Name: Brigham and Women's Hospital Clinical Laboratories

Address: Brigham and Women's Hospital Clinical Laboratories, 75 Francis Street, Amory 2, RM 215, Boston, MA, 02115, USA

Network Affiliation: ACTG, HVTN

Accreditation: CLIA

**Tests Performed**

CD4	Chemistry	Hematology
Histology	Immunology	Metabolic Tests
Microbiology	Pharmacology	Serology
Toxicology	Virology	

Map data ©2019 Google | Terms of Use | Report a map error

● Main Clinic Location ● Laboratory Location

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Content last reviewed on January 01, 2019

Bridge HIV CRS  
HPTN, HVTN, MTN  
Brigham and Women's Hospital Therapeutics Clinical Research Site (BWH TCRS) CRS  
ACTG  
Brigham and Women's Hospital Vaccine CRS (BWH VCRS)  
HVTN  
Bronx Prevention Research Center CRS  
HPTN  
Byramjee Jeejeebhoy Medical College (BJMC) CRS  
ACTG, IMPACT  
Capital Medical Associates, PC CRS  
ACTG (Protocol-Specific)  
CAPRISA eThekweni CRS  
HVTN  
Case Clinical Research Site  
ACTG, HVTN  
Center for Vaccine Development CRS  
IMPACT  
Center of Translational AIDS Research, Lewis Katz School of Medicine at Temple University CRS  
ACTG (Protocol-Specific)  
Centre hospitalier de l'Université Laval CRS  
ACTG (Protocol-Specific)  
Centro de Pesquisas Clínicas IC-HEMUSP CRS  
ACTG (Protocol-Specific), HPTN (Protocol-Specific)  
Centro de Referência e Treinamento DST/AIDS CRS  
ACTG (Protocol-Specific), HPTN (Protocol-Specific)  
Chapel Hill CRS  
ACTG, HPTN

If a site has multiple labs, the user will be able to view each of them by selecting the corresponding tab at the top of the **Laboratory View**.

In the **CRS Laboratory Map-View**, labs are displayed by a green dot with a beaker in the center.

# VIII. Pharmacy View

By clicking “Pharmacy” on the **Left Navigation**, while in The **CRS Profile View**, the user will see pharmacy information for the selected CRS as reported by the site. The Pharmacy View includes the following:

## Pharmacy Information

- Name
- Network Affiliation(s)
- Related CRS(s)

## Pharmacy Capability

- -20° Freezer Storage Approval
- -70° Freezer Storage Approval
- Biosafety Cabinet/Isolator
- Refrigerated Storage Approval
- Room Storage Approval

NIH

National Institute of Allergy and Infectious Diseases

CRS Explorer

Profile

Pharmacy

Laboratory

Population Characteristics

Pharmacy details on this page are reported by the grantees or CRS Leader and should not be considered as a comprehensive representation of each pharmacy. Additional pharmacy information may be provided upon request.

107 - Brigham and Women's Hospital Therapeutics Clinical Research Site (BWH TCRS) CRS

Pharmacy 1

Pharmacy Information

Name:

Brigham & Women's Hosp. Investigational Drug Services

ID#:

60014

Network Affiliation(s):

ACTG, HPTN, HVTN, NICHD-IMPAACT

Related CRS(s):

Pharmacy Capability

-20° Freezer Storage Approval

-70° Freezer Storage Approval

Biosafety Cabinet/Isolator

Refrigerated Storage Approval

Room Storage Approval

Bridge HIV CRS  
HPTN, HVTN, MTN

Brigham and Women's Hospital Therapeutics Clinical Research Site (BWH TCRS) CRS  
ACTG

Brigham and Women's Hospital Vaccine CRS (BWH VCRS)  
HVTN

Bronx Prevention Research Center CRS  
HPTN

Byramjee Jeejeebhoy Medical College (BJMC) CRS  
ACTG, IMPAACT

Capital Medical Associates, PC CRS  
ACTG (Protocol-Specific)

CAPRISA eThekweni CRS  
HVTN

Case Clinical Research Site  
ACTG, HVTN

Center for Vaccine Development CRS  
IMPAACT

Center of Translational AIDS Research, Lewis Katz School of Medicine at Temple University CRS  
ACTG (Protocol-Specific)

Centre hospitalier de l'Université Laval CRS  
ACTG (Protocol-Specific)

Centro de Pesquisas Clínicas IC-HCFMUSP CRS  
ACTG (Protocol-Specific), HPTN (Protocol-Specific)

Centro de Referência e Treinamento DST/AIDS CRS  
ACTG (Protocol-Specific), HPTN (Protocol-Specific)

Chapel Hill CRS  
ACTG, HPTN

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HHS.gov

NIH.gov

NIH/DAIDS.gov

USA.gov

FOIA

Web Policies and Notices

Content last reviewed on January 01, 2019

If a site has multiple pharmacies, the user will be able to view each of them by selecting the corresponding tab at the top of the **Pharmacy View**.

# IX. Population Characteristics

Clicking the “Population Characteristics” on the **Left Navigation** will display information, as reported by the site, related to the potential participant population available. The information includes:

Demographic	Risk Factor	Disease/Condition
<ul style="list-style-type: none"> <li>• Gender</li> <li>• Age</li> <li>• Race</li> <li>• Ethnicity</li> </ul>	<ul style="list-style-type: none"> <li>• MTCT</li> <li>• MSM</li> <li>• Bisexual</li> <li>• Sex Work</li> <li>• Transactional Sex</li> <li>• People Who Inject Drugs</li> <li>• Sero-Discordant Couple</li> <li>• Breastfeeding/Lactating</li> <li>• Substance Abuse</li> </ul>	<ul style="list-style-type: none"> <li>• HIV Uninfected</li> <li>• HIV Exposed Infants</li> <li>• HIV Infected</li> <li>• Clade A</li> <li>• Clade B</li> <li>• Clade C</li> <li>• Clade D</li> <li>• Clade E</li> <li>• Acute HIV Infection</li> <li>• Chronic HIV Infection</li> <li>• Treatment Naive</li> <li>• HIV Related Malignancies</li> <li>• HIV/TB Co-infection</li> <li>• TB</li> <li>• MDR TB</li> <li>• XDR TB</li> <li>• HIV/HBV Co-infection</li> <li>• HBV</li> <li>• HIV/HCV Co-infection</li> <li>• HCV</li> <li>• Infectious Comorbidities</li> <li>• Non-Infectious Comorbidities</li> <li>• Pregnant</li> <li>• Post Menopausal</li> </ul>

National Institute of Allergy and Infectious Diseases

CRS Explorer

Profile

Pharmacy

Laboratory

Population Characteristics

These characteristics are reported by the grantee or CRS Leader and represent the population accessible by this site for clinical research activity.

107 - Brigham and Women's Hospital Therapeutics Clinical Research Site (BWH TCRS) CRS

Demographic	Risk Factor	Disease/Condition
<b>Gender</b> Female Male Transgender	MSM Bisexual Heterosexual People Who Inject Drugs Substance Abuse	HIV Infected Clade B Acute HIV Infection Chronic HIV Infection Treatment Naive HIV Related Malignancies HIV/HBV Co-infection HIV/HCV Co-infection Infectious Comorbidities Non-Infectious Comorbidities Pregnant Post Menopausal
<b>Age</b> Young Adult (18-24) Adult		
<b>Race</b> Asian Black or African American Other White		
<b>Ethnicity</b> Hispanic or Latino Not Hispanic or Latino		

Bridge HIV CRS  
HPTN, HVTN, MTN

Brigham and Women's Hospital Therapeutics Clinical Research Site (BWH TCRS) CRS  
ACTG

Brigham and Women's Hospital Vaccine CRS (BWH VCRS)  
HVTN

Bronx Prevention Research Center CRS  
HPTN

Byramjee Jeejeebhoy Medical College (BJMC) CRS  
ACTG, IMPAAT

Capital Medical Associates, PC CRS  
ACTG (Protocol-Specific)

CAPRISA eThekweni CRS  
HVTN

Case Clinical Research Site  
ACTG, HVTN

Center for Vaccine Development CRS  
IMPAAT

Center of Translational AIDS Research, Lewis Katz School of Medicine at Temple University CRS  
ACTG (Protocol-Specific)

Centre hospitalier de l'Université Laval CRS  
ACTG (Protocol-Specific)

Centro de Pesquisas Clínicas IC-HCFMUSP CRS  
ACTG (Protocol-Specific), HPTN (Protocol-Specific)

Centro de Referência e Treinamento DST/AIDS CRS  
ACTG (Protocol-Specific), HPTN (Protocol-Specific)

Chapel Hill CRS  
ACTG, HPTN

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## SECTION

# D



## Acronyms & Glossary



## -A-

### **AIDS Clinical Trials Group (ACTG)**

The NIAID HIV/AIDS Network focused on therapeutics research for HIV/AIDS and HIV-associated infections in adults.

### **ACTG Protocol Specific (PS)**

Sites which are restricted to conducting a specified protocol(s) for the ACTG network. New protocol work is based upon evaluation and approval by DAIDS and Network.

### **Active Site**

Site that has been evaluated and approved by DAIDS to participate in one or more NIAID HIV/AIDS Network trials.

### **Accreditation**

The organization providing the accreditation for the selected laboratory if applicable.

### **Associate Pharmacist (AP)**

A licensed/registered pharmacist who performs the day-to-day pharmacy activities and study product management including but not limited to the procurement, storage, preparation, dispensing and final disposition of study products for the DAIDS funded and/or sponsored clinical trial(s), when the Pharmacist of Record is absent.

## -C-

### **CD4**

Refers to tests that measure the number of CD4 cells (the “helper” T-cell population infected and killed by HIV) in a blood sample and is a laboratory marker of the strength of a person’s immune system. Tests examine the percentage and absolute count of CD4 and CD8 cells in peripheral blood specimens.

### **Chemistry**

The area of clinical pathology that is generally concerned with the chemical analysis of bodily fluids for diagnostic and therapeutic purposes.

## **CLIA**

Clinical Laboratory Improvement Amendments.

## **CAP**

College of American Pathologists.

## **Clinical Research Site (CRS)**

A medical facility (e.g. hospital, outpatient clinic, community health center, private practice, local health department clinic) that participates in NIAID HIV/AIDS Networks clinical trials where participant recruitment and retention, protocol management and other clinical care and research activities are conducted.

## **Clinical Trials Insurance (CTI)**

Insurance for injury or damage to study participants that may be required by national guidelines of countries participating in clinical trials.

## **Clinical Trials Unit (CTU)**

Unit that receives grant funding from NIAID and has ultimate administrative, financial, and scientific responsibility for the conduct of DAIDS Networks trials at its Clinical Research Site(s).

## **CNAS**

China National Accreditation Services.

## **Contact PI**

Person through which all grant communications should flow, whose role is to provide leadership to the CTU as well as ensure efficient communication to the rest of the multi-PI team.

## **CPQA PT Program for Clinical Pharmacology Testing**

NIAID Clinical Pharmacology Quality Assurance Program – provides external quality assurance for laboratories performing pharmacology testing.

## **CRS Leader**

Main point-of-contact for the management of DAIDS Network clinical research trials at the site.

## **CTU Name**

The name on the CTU grant application.



## Cytology

The branch of life science that deals with the study of cells in terms of structure, function and chemistry.

**-D-**

## Division of AIDS (DAIDS)

DAIDS is within the NIAID and is the Sponsor for the NIAID HIV/AIDS Clinical Trials Unit and Sites as well as the NIAID HIV/AIDS Research Networks.

**-E-**

## EQAPOL PT Programs for Immunological Assays

External Quality Assurance Program Oversight Laboratory – provides quality assurance for more advanced immunological testing including ELISPOT, Immunohistochemistry and others.

**-F-**

## Full Network Affiliation

When a CRS is part of a Clinical Trials Unit (CTU) grant and may participate in all Network approved protocols as appropriate.

**-H-**

## Hematology

The branch of medicine concerned with the study of the cause, diagnosis, treatment, and prevention of diseases related to blood. Laboratory testing frequently involves complete blood count as well as white blood cell differential.

## Histology

The study of the microscopic anatomy (microanatomy) of cells and tissues of plants and animals. It is commonly performed by examining cells and tissues under a light microscope or electron microscope, the specimen having been sectioned (cut into a thin cross section with a microtome), stained, and mounted on a microscope slide.

## **HIV Prevention Trials Network (HPTN)**

The NIAID HIV/AIDS Network focused on integrated strategies to prevent HIV acquisition and transmission.

## **HIV Vaccine Trials Network (HVTN)**

The NIAID HIV/AIDS Network focused on the development of vaccines to prevent HIV infections globally.

## **HPTN Protocol Specific (PS)**

Sites which are restricted to conducting a specified protocol(s) for HPTN network. New protocol work is based upon evaluation and approval by DAIDS and Network.

## **HVTN Protocol Specific (PS)**

HVTN Protocol Specific sites are restricted to conducting a specified protocol(s) for the HVTN network. New protocol work is based upon evaluation and approval by DAIDS and Network.

**-I-**

## **Immunology**

The study of all aspects of the immune system, including its structure and function, disorders of the immune system, blood banking, immunization and organ transplantation. Examples of HIV-related immunologic tests include the EIA, Western Blot, detuned ELISA assay, ELISPOT and ICC.

## **IMPAACT Protocol Specific (PS)**

Sites which are restricted to conducting a specified protocol(s) for the IMPAACT network. New protocol work is based upon evaluation and approval by DAIDS and Network.

## **Institutional Biosafety Committee**

The committees responsible for the oversight of recombinant DNA research.

## **Institutional Review Board (IRB)**

A committee that performs ethical review of proposed research to be conducted at an Institution and is registered with the Office of Human Research Protections (OHRP).

## **International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT)**

The NIAID HIV/AIDS Network focused on decreasing incident HIV and HIV-associated infections, as well as decreasing morbidity and mortality due to HIV, HIV-associated infections and comorbidities among infants, children, adolescents and pregnant/postpartum women.

## **IQA Cryopreservation PT Program**

NIAID Immunology Quality Assurance Program – provides external quality assurance [proficiency testing] to ensure proper processing and cryopreservation of PBMCs.

## **IQA U.S. CD4 PT Program**

NIAID Immunology Quality Assurance Program – provides external quality assurance [proficiency testing] for CD4 testing in the US.

## **IQA/UKNEQAS Non-US CD4 PT Program**

NIAID Immunology Quality Assurance Program – provides external quality assurance [proficiency testing] for CD4 testing outside the US through partnership with UKNEQAS.

**-K-**

## **KENAS**

Kenya Accreditation Service.

**-L-**

## **Laboratory Audits by DAIDS Contractor**

Provides laboratory assessments of Good Clinical Laboratory Practices for non-US and some US laboratories.

## **Laboratory Infrastructure**

This section includes general details pertaining to the laboratory(ies) at this site.

## **Laboratory Network Affiliation**

The Network for which the selected laboratory has performed protocol-specific tests.

## Laboratory Related Sites

Laboratories that serve multiple DAIDS clinical research sites.

## Languages

Language(s), other than English, that must be used for informed consent documents at this site.

## LDMS #

The number assigned to each DAIDS-approved laboratory to facilitate electronic transfer of specimen information.

**-M-**

## Metabolic Tests

Refers to tests that analyze chemical changes that take place in a cell or an organism to produce energy and basic materials needed for important life processes. Examples of metabolic tests include cholesterol, triglycerides, and lipase.

## Microbicides Trials Network (MTN)

The NIAID HIV/AIDS Network focused on microbicides to prevent sexual transmission of HIV infection.

## Microbiology

The study of minute living organisms, including protozoan, algae, fungi, bacteria, that are usually too small to be seen with the naked eye. Examples of microbiology tests include syphilis, cryptosporidiosis, MTB, and malaria.

## MTN Protocol Specific (PS)

Sites which are restricted to conducting a specified protocol(s) for the MTN network. New protocol work is based upon evaluation and approval by DAIDS and Network.

## Multiple Investigator(s) (Multi-PIs)

NIH grant model which (a) allows applicants and their institutions to identify more than one PI on a single grant application and; (b) encourages collaboration among equals when addressing a scientific problem. If a CTU grant includes multiple investigators, a Contact PI is assigned and is designated as the recipient of all grant-related communications (see [Contact PI](#)).

## **NABL**

National Accreditation Board of Testing and Calibration Laboratories, Quality Council of India.

## **National Regulatory Authority(ies)**

This is a required level of review/approval for the site to initiate clinical research protocols. It is in addition to the Local Institution-level review or ethics committee.

## **Network**

Designation indicates a CRS that is affiliated as a full partner with one or more NIAID HIV/AIDS Network.

## **NIAID Reserve**

Designation indicates a CRS that is not currently affiliated as a full partner with any of the NIAID HIV/AIDS Networks. These sites may be of particular interest for future NIAID Network protocol activity.

## **NIAID ClinRegs**

An online public database of country-specific clinical research regulatory information that enables users to explore and compare regulations across different countries. The website was created and is maintained by NIH's National Institute of Allergy and Infectious Diseases (NIAID).

## **NIAID Networks**

The NIAID Clinical Trials Network Leadership Operations Center grantees have overall responsibility for developing, implementing, and adapting the network's clinical research agenda to address NIAID's HIV/AIDS scientific priorities, as well as overseeing and managing the network's scientific/clinical research activities and associated laboratory and statistical/data management support functions. There are five NIAID HIV/AIDS networks:

- AIDS Clinical Trials Group (ACTG)
- HIV Prevention Trials Network (HPTN)
- HIV Vaccine Trials Network (HVTN)
- International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT)
- Microbicide Trials Network (MTN)

## **HVTN Cryopreservation Monitoring Program**

HVTN program to provide external quality assurance [proficiency testing] to ensure proper processing and cryopreservation of PBMCs.

### Office of Clinical Site Oversight (OCSO)

The DAIDS office responsible for facilitating the clinical research of the DAIDS scientific programs by overseeing clinical sites associated with the NIAID-sponsored HIV/AIDS clinical trials networks.

### Other IRB

Multiple IRBs may be associated with a single institution.

### PALC-SBPC

Clinical Laboratory Accreditation Program of Brazil.

### Pharmacist of Record (PoR)

A licensed/registered pharmacist who performs the day-to-day pharmacy activities and study product management including but not limited to the procurement, storage, preparation, dispensing and final disposition of study products for the DAIDS funded and/or sponsored clinical trial(s).

### Pharmacology

The study of drugs, including their properties, uses, metabolism and effects in the body. Tests examine drug levels in blood and other compartments at various times after dosing.

### Pharmacy

Any facility, building, or room used by pharmacists to perform one or more of the following functions: storage, preparation, dispensing, management of study products, (examples: hospital pharmacy or institutional pharmacy, dispensary, drug storage unit, drug store).

### Pharmacy Establishment Plan (PEP)

The PoR must complete a Division of AIDS (DAIDS), Pharmaceutical Affairs Branch (PAB) Pharmacy Establishment Plan (PEP) for each pharmacy associated with a Clinical Research Site (CRS). The PEP determines if the pharmacy has the required DAIDS PAB processes and procedures in place. The PEP also determines if the facilities and equipment necessary for studies involving controlled room temperature, refrigerated Storage, -20° C freezer Storage, -70° C freezer Storage, and the use of a biosafety cabinet/isolator are available.

## Population Characteristics

Clinic demographics and research enrollment experience as reported by each CRS to describe the potential participants accessible at the site.

## Principal Investigator (PI)

The PI is named on the NIH Clinical Trials Unit (CTU) grant application and is responsible for managing all aspects of the CTU and associated CRSs. In some cases, the responsibilities of a PI are shared among multiple Investigators (see [Multi-PI](#)); however a single individual within the multi-PI group will be assigned as the single point of contact (see [Contact PI](#)).

## Program Officer

Program Officer - the NIAID/DAIDS/OCSO staff member who is responsible for administering the CTU grant and monitoring clinical trial activities to ensure all studies are conducted according to NIAID standards. The Program Officer is the point-of-contact listed in each site profile for questions or comments.

## Protocol Specific (PS) Sites

Sites funded on a case-by-case basis by DAIDS to conduct a specific network protocol(s). Sites that have a full network affiliation may also have a PS designation for a different network, or sites may be PS only.

**-Q-**

## Quality Assurance

Services that the selected laboratory receives in order to maintain quality assurance monitored by DAIDS and/or its contractors.

**-S-**

## SANAS

South African National Accreditation System.

## SAS

Swiss Accreditation Service.

## Serology

The scientific study of serum and other bodily fluids. In practice, the term usually refers to the diagnostic identification of antibodies in the serum. Generally used to diagnose infectious diseases.

## Site ID

Unique numeric ID assigned to each DAIDS CRS.

## SMILE Oversight of Test Proficiency and GCLP

Patient Safety Monitoring in International Laboratories – ensures laboratory external quality assurance programs are in place and monitors performance for non-US labs.

## Specimen Processing

Refers to the receipt, identification, preparation, and storage of samples, such as tissue, blood, and urine, which are used for analysis and diagnosis.

**-T-**

## TB

Refers to the capacity of the laboratory to perform testing for diagnosis of Mycobacterium tuberculosis (TB), as well as other TB-related testing (drug susceptibility, interferon gamma release assay, etc.).

**-V-**

## Viable PBMC Processing

Refers to the ability of laboratories to isolate, freeze and store PBMCs that will remain viable and can be thawed and tested in functional assays at a later time point.

## Virology

The study of viruses. Examples of HIV virology tests include HIV RNA PCR, HIV DNA PCR, HIV drug resistance (phenotypic and genotypic), HIV p24 antigen, viral identification and quantification in genital secretions. Non-HIV virology tests include HPV, CMV, HepB, HepC.

## VQA PT Programs for Virologic Assays

NIAID Virology Quality Assurance Program - provides external quality assurance [proficiency testing] for HIV related virologic assays.