



# CCTS Guide for Clinical Research Professionals

## Touchpoints with the Center for Clinical and Translational Science (CCTS)

# Jennifer A. Croker, PhD

Senior Administrative Director, CCTS  
Assistant Professor of Medicine

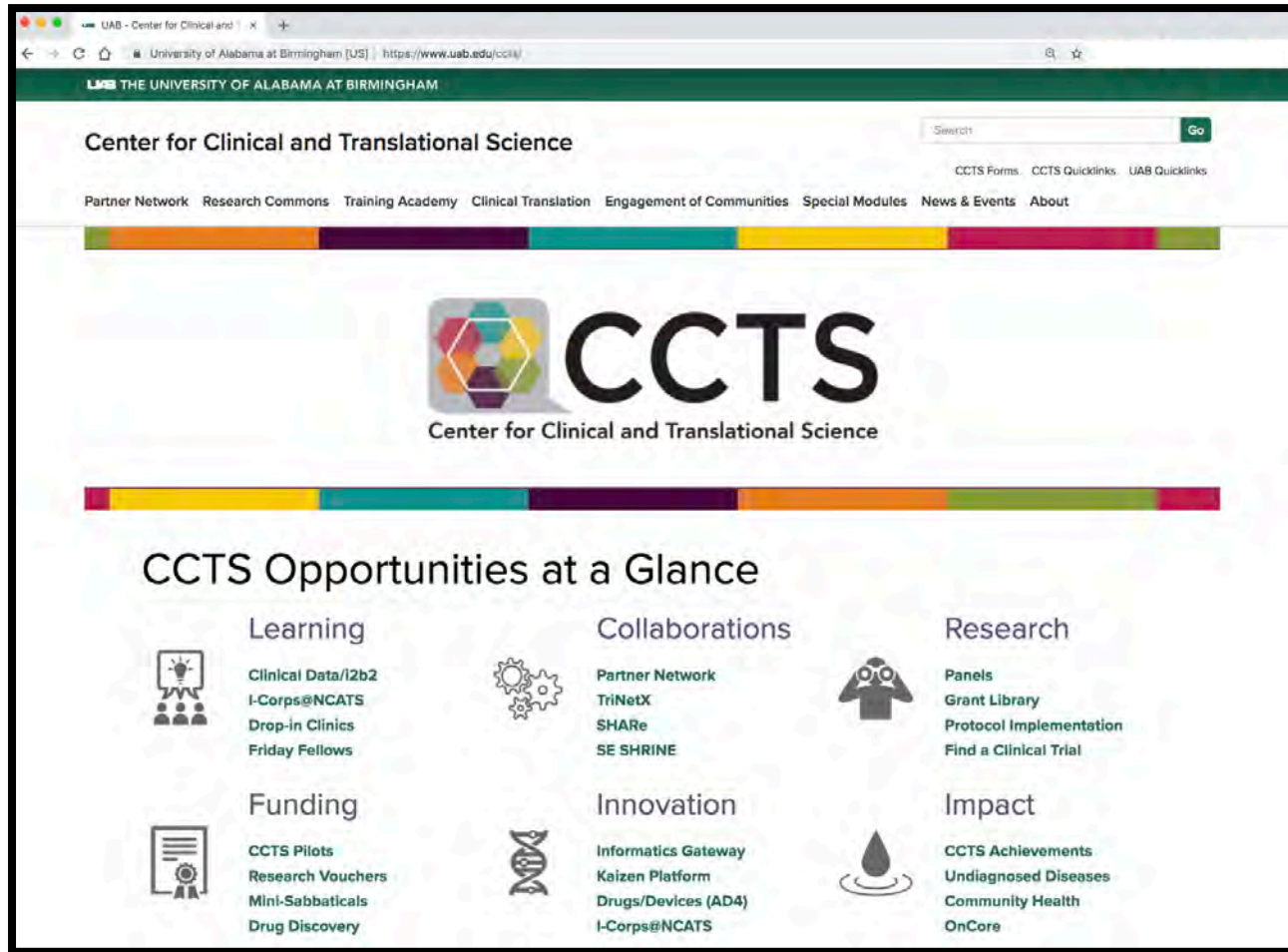


[PollEv.com/jcroker164](https://www.poll-ev.com/jcroker164)

ACCELERATE. INNOVATE. DISSEMINATE. **WITH YOUR CCTS.**



# Stay Connected



[www.uab.edu/ccts](http://www.uab.edu/ccts)



205-934-7442



[ccts@uab.edu](mailto:ccts@uab.edu)



SHEL 171 – 1825 University Blvd.



[@cctsnetwork](https://twitter.com/cctsnetwork)



Search YouTube: [cctsnetwork](https://www.youtube.com/cctsnetwork)

*Science through Synergy*

## Center for Clinical and Translational Science

Search  Go

CCTS Forms CCTS Quicklinks CCTS Video Channel

Partner Network Research Commons Training Academy Clinical Translation Engagement of Communities Special Modules News & Events About

Information and messages about UAB's re-entry to campus and Ways to help



Stay informed with updates surrounding CCTS-related events, meetings, and trainings that are affected by the COVID-19 outbreak.


[Click for Upcoming Event Information](#)

## CCTS Opportunities at a Glance


**Learning**

 CCTS Video Channel  
Clinical Data/i2b2  
TIERS  
Drop-in Clinics  
CRSP Trainings

**Collaborations**

 Partner Network  
Trial Innovation Network  
SHARe  
SE SHRINE

**Research**

 Panels  
Grant Library  
Protocol Implementation  
Find a Clinical Trial

**Funding**

 CCTS Pilots  
Research Vouchers  
Mini-Sabbaticals  
Drug Discovery

**Innovation**

 Informatics Gateway  
Kaizen Platform  
Drugs/Devices (AD4)  
I-Corps@NCATS

**Impact**

 CCTS Achievements  
Undiagnosed Diseases  
Community Health  
OnCore

# About ... Become a Member

## Subscribe to the CCTS Digest

First Name \*  Last Name \*

Email Address \*

School, Unit or Department

Affiliated Organization

Please select...

What is the Center for Clinical and Translational Science?



# Rolodex

**Questions about Where to Start?**

[CCTS@uab.edu](mailto:CCTS@uab.edu)

**Questions about Learning Opportunities:**

[CRSPtraining@uabmc.edu](mailto:CRSPtraining@uabmc.edu)

**Questions about Clinical Research  
Workflows and Procedures?**

[cctsclinical@uab.edu](mailto:cctsclinical@uab.edu)

**Questions about Recruitment & Retention?**

[CRSPrecruitment@uabmc.edu](mailto:CRSPrecruitment@uabmc.edu)

**Questions about ClinicalTrials.Gov?**

[CCTSClinicalTrials.govHELP@uabmc.edu](mailto:CCTSClinicalTrials.govHELP@uabmc.edu)

**Questions about OnCore?**

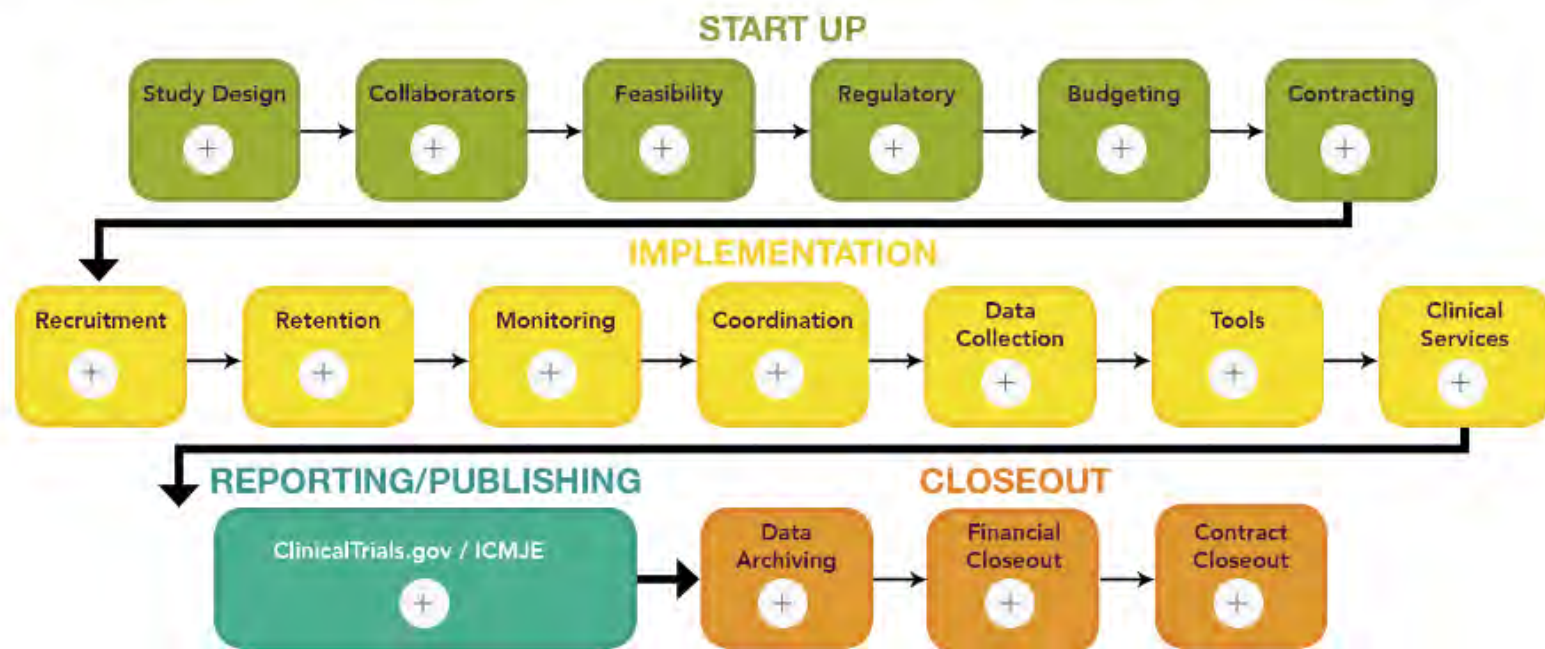
[Oncore@uabmc.edu](mailto:Oncore@uabmc.edu)

[OnCoreCalendars@uabmc.edu](mailto:OnCoreCalendars@uabmc.edu)

[OnCoreTraining@uabmc.edu](mailto:OnCoreTraining@uabmc.edu)

# Clinical Trials Lifecycle

CCTS supports every stage of the clinical trial lifecycle. Just click any box to learn more.





**This is you.**







# CCTS Training Academy



# CCTS Training Academy

## Clinical Research Trainings

Clinical Research Support Program (CRSP) Educational offerings provide academic training in the principles essential for success in the clinical research environment. In-person, classroom-based, and online courses relevant to investigators, study coordinators, financial staff, regulatory coordinators, and other research staff are available, with emphases on Good Clinical Practices (GCP), compliance, and other key topics.

For specific information on upcoming CRSP events such as topics, presenters, Zoom details, and more, please visit our [Upcoming Events page](#). You can also revisit past CRSP training opportunities by visiting the our CCTS Video Channel.

[Click Through](#) the Items Below to Explore our Training Opportunities

### CCTS Lunch & Learn

[Research Orientation Program \(ROP\)](#)

[Research Training Program \(RTP\)](#)

[Clinical Investigator Training Program \(CITP\)](#)

[Research Seminar Series](#)

[CITP on the Go Podcast](#)



[OnCore](#)

## CCTS LUNCH & LEARN

- **What:** A presentation of updates from various UAB research entities, including the CCTS, Office of Sponsored Programs (OSP), Institutional Review Board (IRB), OnCore, and more.
- **Why:** To provide critical guidance on new or changing requirements and support the conduct of clinical research at UAB (and beyond).
- **When:** Quarterly
- **Who:** All clinical research teams, regardless of study type or foci, are encouraged to send at least one person to attend and take back updates to their team and home office.
- **Upcoming Date(s):** April 11, 2023

[LEARN MORE](#)

Click to view  
CRSP Education  
2022-2023 Dates



## CLINICAL RESEARCH SUPPORT PROGRAM

Learn more at [www.uab.edu/ccts/clinical-translation/clinical-services/crsp](http://www.uab.edu/ccts/clinical-translation/clinical-services/crsp)

### SAVE THE DATES! CRSP EDUCATION DATES

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#### RESEARCH TRAINING PROGRAM (RTP)

FALL 2023 DATES	SPRING 2024 DATES
August 29	April 16
September 5	April 23
September 19	April 30
September 26	May 7
October 3	May 14
October 10	May 21

#### CLINICAL INVESTIGATOR TRAINING PROGRAM (CITP)

FALL 2023 DATES	SPRING 2024 DATES
Morning Sessions	Afternoon Sessions
October 24	February 6
October 31	February 13
November 7	February 20
November 14	February 27
November 28	March 5

#### 2023-2024 CCTS LUNCH & LEARNS


MONTH	DATES
September	12
December	12
April 2024	9

#### 2023-2024 RESEARCH ORIENTATION PROGRAM (ROP)

MONTH	DATES
August	24
October	26
January 2024	25
March	14
May	23

#### 2023-2024 SPECIAL TOPICS IN CLINICAL TRIALS / RESEARCH SEMINAR SERIES

MONTH	DATES (1st THURSDAYS)	DATES (3rd THURSDAYS)
September	7	21
October	5	19
November	2	16
December	7	Break
January 2024	4	18
February	1	15
March	7	21
April	4	18
May	2	16
June	6	

**CCTS**  
Center for Clinical and Translational Science  
[uab.edu/ccts/clinical-translation](http://uab.edu/ccts/clinical-translation) | [ccts@uab.edu](mailto:ccts@uab.edu) | 205-934-7442



# CCTS Training Academy

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Research Training Program (RTP)

Clinical Investigator Training Program (CITP)

Research Seminar Series

CITP on the Go Podcast

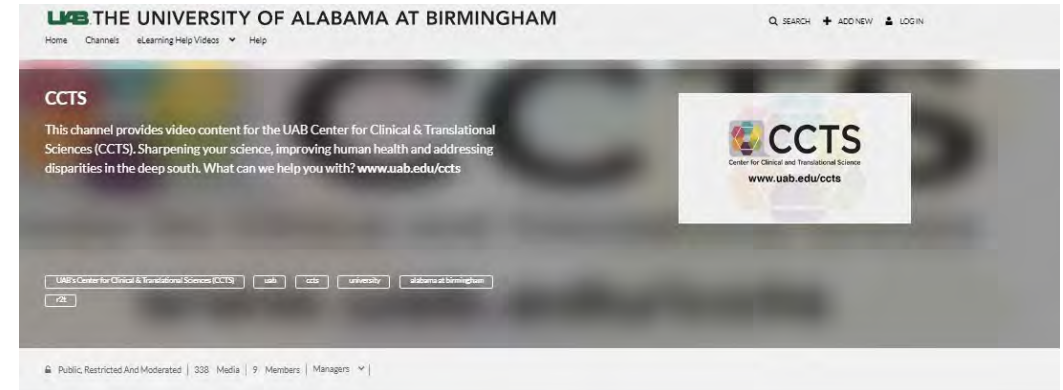
OnCore

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[LEARN MORE](#)

Click to view  
CRSP Education  
2022-2023 Dates



### CRSP EDUCATION: CLINICAL BILLING



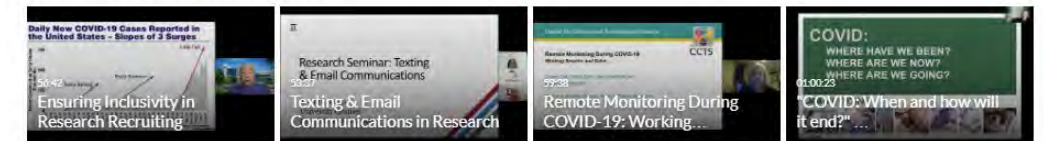
### CRSP EDUCATION: CLINICALTRIALS.GOV



### CRSP EDUCATION: COORDINATOR RESOURCES



### CRSP EDUCATION: COVID RESOURCES



<https://mediaspace.uab.edu/channel/CCTS/43146511>



# Duty Calls....



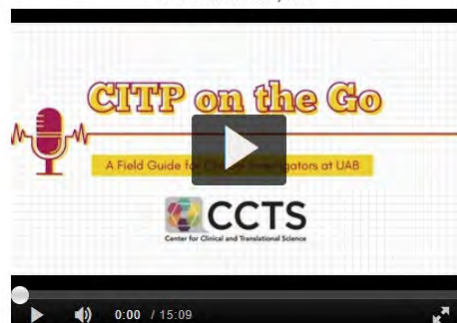


# CITTP on the Go

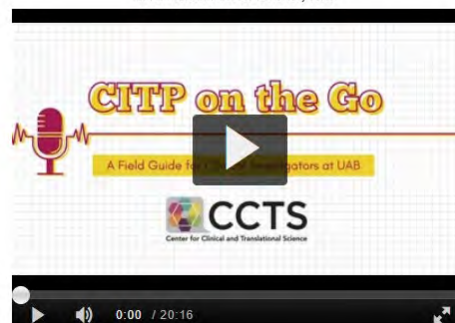


A Field Guide for Clinical Investigators at UAB

Episode 1: Recruitment and Retention  
with Dana Rizk, MD



Episode 2: Obtaining Informed Consent  
with Mark Dransfield, MD



- Episode 3: Developing a Team and Team Communications**
- Episode 4: Role and Responsibilities of a Principal Investigator**
- Episode 5: ClinicalTrials.gov: Getting Started, Protocol ID & ID'ing PI**
- Episode 6: ClinicalTrials.gov: Arms and Interventions**
- Episode 7: ClinicalTrials.gov: Study Status**
- Episode 8: ClinicalTrials.gov: Outcome Measures**
- Episode 9: ClinicalTrials.gov: Successful Sign-off**

**What else do you want to hear?**





# LUNCH & LEARN

2<sup>nd</sup> Tuesdays | 11:30am – 1pm | April - September – December

<https://www.uab.edu/ccts/clinical-research/trainings/ccts-lunch-learns>

Networking. Essential Updates.

# All you need a click away...



UAB Clinical Research Onboarding	+
UAB Research Administration Offices	+
COVID-19 Support Documents & Resources	+
Resources for Conducting Clinical Research	+
Source Documents, Tools & Templates	+
Investigator Toolkit	+
Recruitment & Retention	+
Study Coordinator Trial Starter Kit	+
Budget Toolkit	+
Corrective Action and Preventative Plan (CAPA)	+
Standard Operating Procedures (SOPs) Templates	+
Research Seminar Series Archive (CRSP Education Videos)	+
IND/IDE Consultation Team	+
ClinicalTrials.gov	+

<https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk>

are  
you  
reading?

Over 2,000 UAB faculty members & research staff receive the Trending in Trials e-newsletter to stay at the cutting edge.

This 60-second read from the UAB Clinical Trials Administration Committee (CTAC) supplies tools and information that reduce barriers to clinical trial success.



Scan to sign up  
or visit [forms.uab.edu/255](https://forms.uab.edu/255)



# All you need a click away...

## WELCOME TO THE CLINICAL TRIALS KIOSK: EVERYTHING YOU NEED FOR CLINICAL TRIALS RESEARCH



- UAB Clinical Research Onboarding
- UAB Research Administration Offices
- COVID-19 Support Documents & Resources
- Resources for Conducting Clinical Research
- Source Documents, Tools & Templates
- Investigator Toolkit
- Recruitment & Retention
- Study Coordinator Trial Starter Kit
- Budget Toolkit
- Corrective Action and Preventative Plan (CAPA)
- Standard Operating Procedures (SOPs) Templates
- Research Seminar Series Archive (CRSP Education Videos)
- IND/IDE Consultation Team
- ClinicalTrials.gov

<https://www.uab.edu/ccts/clinical-research/clinical-trial-kiosk>

Blood Collection & Handling

Consent Form Prep

Consent Process Checklist  
with Assent

He

Adverse Event Log

Informed Consent Form  
Version Tracking Log

IRB Review History Log

Laboratory Flow Sheet

Monitor Log

Protocol/Other Training Log

Protocol Deviation Log

Screening and Enrollment  
Log

Serious Adverse Event Log

Significant IRB  
Correspondence Log

Study Identification Page

Study Personnel  
Signatures/Responsibility  
Log

Subject Contact Information

Subject Screening Log

Subject Study Drug  
Accountability Record

Sample Patient/Participant  
Information Sheet

# Office Hours: *No need to recreate the wheel*

## **IRB**

### **Office Hours**

Thursdays, biweekly  
11am-1pm | Virtual

## **OSP**

### **Office Hours**

1<sup>st</sup> Thursdays  
2-3pm | Virtual

## **OnCore**

### **Q&A Sessions**

Tuesdays  
11am-1pm | Virtual

## **BERD Clinics**

Wed. 11:30am-1pm  
Fridays 8:30-11:30am  
In-Person

## **Research Data Group**

### **Office Hours**

1<sup>st</sup> & 3<sup>rd</sup> Wednesdays  
2-3:30pm | Virtual

## **Innovation**

### **Office Hours**

Wednesdays  
1-2pm | Virtual



# Budget Development Workshop

June 7-8, 2023, SHEL 105 (capped) / Zoom



- Understand how to deconstruct clinical research (trial) protocols
- Anticipate start-up fees, data collection, patient care or procedures, personnel and site costs
- Master the art of negotiation
- Gain other essential skills to ensure the full support of a project from start up through reporting

**Questions:** [CRSPtraining@uabmc.edu](mailto:CRSPtraining@uabmc.edu) **Register:** [https://uab.co1.qualtrics.com/jfe/form/SV\\_a4ZdKdqnoIt2D0a](https://uab.co1.qualtrics.com/jfe/form/SV_a4ZdKdqnoIt2D0a)





# ClinicalTrials.gov

## ClinicalTrials.gov PRS Protocol Registration and Results System

FDAAA  
TrialsTracker

Log In to PRS: <https://register.clinicaltrials.gov/>

Need an account, advice, or help? Contact [CCTSClinicalTrials.govHELP@uabmc.edu](mailto:CCTSClinicalTrials.govHELP@uabmc.edu).

### Helpful Hints:

- Logging In – Organization: UAB
- New Record – Unique Protocol ID is the UAB IRB number (IRB-3000#####)
- Responsible Party – Principal Investigator

### Resources:

- Is my study a clinical trial?
- Cover Sheet Template Download
- Results Entry Checklists and Templates

### ClinicalTrials.gov External Resources:

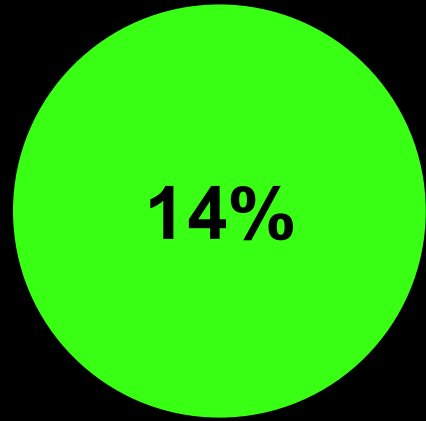
Submit Studies to ClinicalTrials.gov PRS  
Why Should I Register and Submit Results?  
FDAAA 801 and the Final Rule  
How to Apply for a PRS Account  
How to Register Your Study  
How to Edit Your Study Record  
How to Submit Your Results  
Frequently Asked Questions  
Support Materials

### CRSP EDUCATION: CLINICALTRIALS.GOV



<https://www.uab.edu/ccts/clinical-research/clinicaltrials-gov>

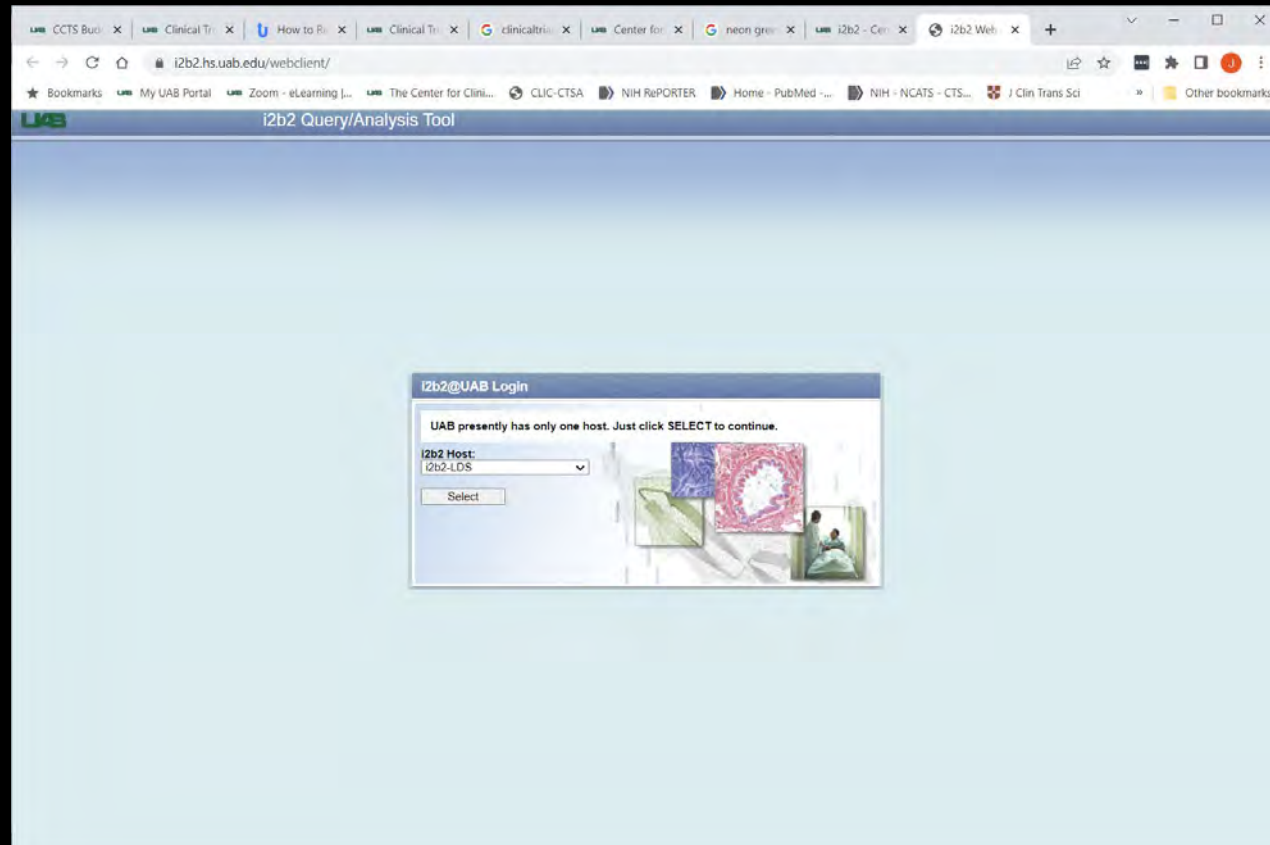




The overall  
clinical trial  
success rate.  
Many studies fail  
because they  
lack participants.

# CCTS Informatics

*Cohort Feasibility (No Special IRB needed)*





Terms Find Trm Info Workplace Queries Find Qry

We have reorganized the i2b2 ontology - it was getting too long, too confusing, and did not help users quickly find what they needed. We didn't remove any concept groups - they are all still here. But if you can't find what you need, please email [ResearchData@uabmc.edu](mailto:ResearchData@uabmc.edu) and we will help you.

- Patient Details - 2,574,878
- Visit Details - 10,590,877
- Diagnoses - ICD10, ICD9, SNOMED [←New](#)
- Procedures - CPT, ICD10, ICD9 [←New](#)
- Lab Test and Results - LOINC, UABLABs [←New](#)
- Medications - RxNorm [←New](#)
  - Medications - RxNorm Organization - 738,164
    - Information about this folder and its contents
    - Drug products by VA class - 738,164
    - UAB Custom Med Groups
  - Medications - UAB Order Catalog Organization
- Phenotype Library
- Other Clinical Data Domains - Allergy, Radiology, Surgery, Tumor Registry, Vital Signs, etc. [←New](#)
- Geographic and Social Determinants Criteria [←New](#)
  - US Area Deprivation Index - State Deciles and National Percentiles
    - Area Deprivation Index National Percentiles
    - Area Deprivation Index State Deciles
      - \* LEAST Disadvantaged - Area Deprivation Index State Decile Value is 1
      - \* MOST Disadvantaged - Area Deprivation Index State Decile Value is 10
      - Area Deprivation Index State Decile Value is 2
      - Area Deprivation Index State Decile Value is 3
      - Area Deprivation Index State Decile Value is 4
      - Area Deprivation Index State Decile Value is 5
      - Area Deprivation Index State Decile Value is 6
      - Area Deprivation Index State Decile Value is 7
      - Area Deprivation Index State Decile Value is 8
      - Area Deprivation Index State Decile Value is 9
  - US Census - American Community Survey Data
  - US Food Access Research Atlas (low access to healthy food)
- Patient Reported Data - Social History, PRO [←New](#)
- BioSpecimen Collection Data
- Detailed Data - PowerForms, Clinical Events, Orders, Rheumatology [←New](#)
- Cohorts of Interest and Research Generated Data - AGHL Covid [←New](#)

Query Tool

Query Name: 18--Essen-\* MOS@17:26:56

Query Timing: Treat all groups independently

Group 1			Group 2			Group 3		
Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude
Treat Independently			Treat Independently			Treat Independently		
18-34 years old			Essential (primary) hypertension (ICD10:I10) - 327,940			* MOST Disadvantaged - Area Deprivation Index State Decile Value is 10		
one or more of these			AND			one or more of these		
			AND			one or more of these		

Run Query

Clear

3 Groups

New Group

Show Query Status

Graph Results

Query Report

Number of patients

858

For Query 18--Essen-\* MOS@17:26:56"

# CCTS Informatics

*Request Cohort Details (IRB Approval Required)*

The screenshot shows the CCTS Informatics website. The header includes the University of Alabama at Birmingham logo and the Center for Clinical and Translational Science. The main navigation bar lists various resources like Partner Network, Research Commons, Training Academy, Clinical Research, Engagement of Communities, Special Modules, News & Events, and About. The Research Commons section is highlighted with a banner that reads "RESEARCH COMMONS" and "sharpening science to accelerate the pace of discovery". Below this, the Informatics section is introduced, stating that CCTS Informatics provides resources and expertise to support biomedical collaboration and consultation across the translational research spectrum. A table titled "Data Access and Support" is displayed, detailing various data access options and their associated data types.

	Analyst-facilitated Data Access	i2b2 Self-Service	TriNetX Research™	National COVID Cohort Collaboration (N3C)	ACT Network	One Florida*
Data Type	EHR, inclusively	Significant* reflection of EHR-structured	Limited Structured data	Structured data related to COVID-19 (e.g.,	Structured data (labs, meds,	EHR, inclusively



# CCTS Informatics

## *Request Cohort Details (IRB Approval Required)*

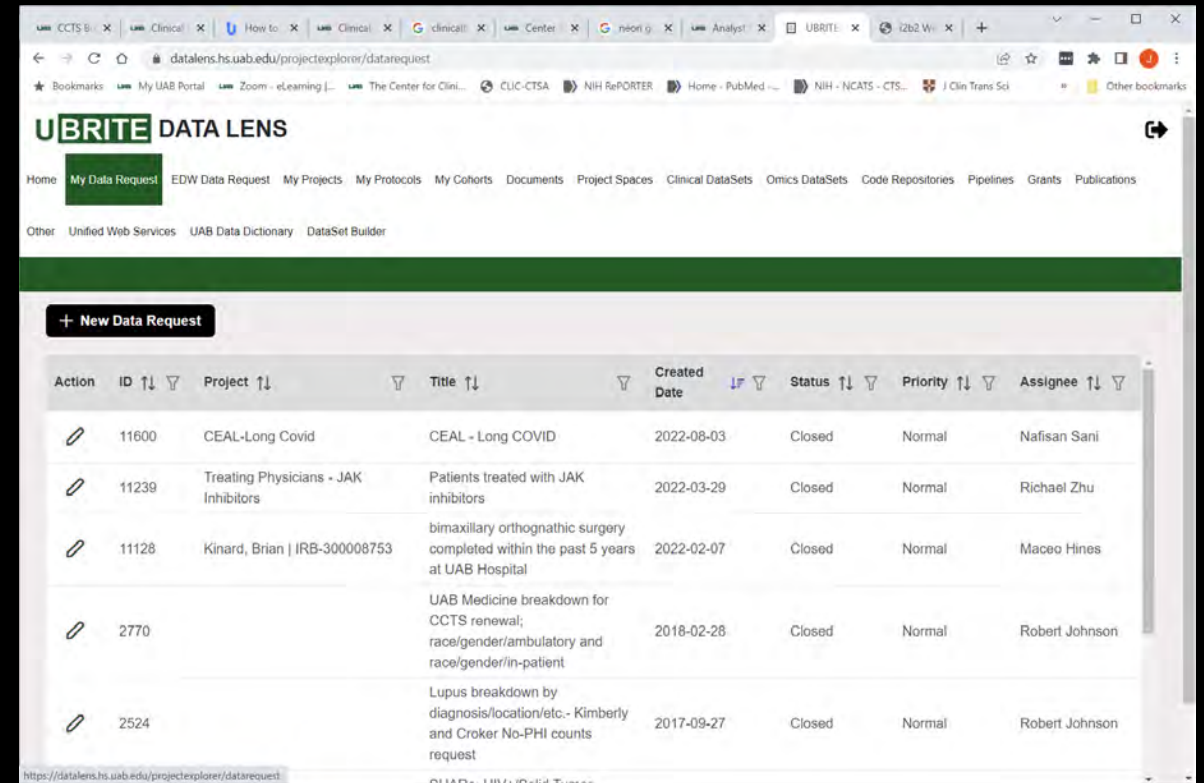
## DataLENS

How to Log in to DataLENS  
Requesting Datasets  
Troubleshooting

+

+

+



The screenshot shows the UBRITE DataLENS web application interface. The header includes the logo and navigation links. The main content area displays a table of data requests with columns for Action, ID, Project, Title, Created Date, Status, Priority, and Assignee. The table lists five requests, all with a status of 'Closed'.

Action	ID	Project	Title	Created Date	Status	Priority	Assignee
	11600	CEAL-Long Covid	CEAL - Long COVID	2022-08-03	Closed	Normal	Nafsan Sani
	11239	Treating Physicians - JAK Inhibitors	Patients treated with JAK inhibitors	2022-03-29	Closed	Normal	Richael Zhu
	11128	Kinard, Brian   IRB-300008753	bimaxillary orthognathic surgery completed within the past 5 years at UAB Hospital	2022-02-07	Closed	Normal	Maceo Hines
	2770		UAB Medicine breakdown for CCTS renewal; race/gender/ambulatory and race/gender/in-patient	2018-02-28	Closed	Normal	Robert Johnson
	2524		Lupus breakdown by diagnosis/location/etc.- Kimberly and Croker No-PHI counts request	2017-09-27	Closed	Normal	Robert Johnson

# COME TOGETHER

- How to Be in the Know
- Who to Contact
- Being Part of a Community of Practice
- Access Learning Opportunities at all Stages
- Leverage Resources to Make your Work Easier
- Take Advantage of Specialized Guidance

**... what else can be done to help you and your band thrive?**

# STAY CONNECTED

Receive the CCTS Newsletter: [\*\*go.uab.edu/JoinTheCCTS\*\*](https://go.uab.edu/JoinTheCCTS)

Follow us on Twitter: [\*\*@cctsnetwork\*\*](https://twitter.com/cctsnetwork)

Check out upcoming events: [\*\*go.uab.edu/cctsevents\*\*](https://go.uab.edu/cctsevents)

Catch past events anytime: [\*\*go.uab.edu/cctsvideochannel\*\*](https://go.uab.edu/cctsvideochannel)





Thank you for joining!