



CCTS Lunch & Learn

September 17,
2019

CENTER FOR CLINICAL & TRANSLATIONAL SCIENCE

AUBURN UNIVERSITY | HUDSONALPHA INSTITUTE FOR BIOTECHNOLOGY | LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER | PENNINGTON BIOMEDICAL RESEARCH CENTER | SOUTHERN RESEARCH
TULANE UNIVERSITY | TUSKEGEE UNIVERSITY | UNIVERSITY OF ALABAMA | UNIVERSITY OF ALABAMA AT BIRMINGHAM | UNIVERSITY OF MISSISSIPPI MEDICAL CENTER | UNIVERSITY OF SOUTH ALABAMA



Agenda

Introduction/Welcome- Meredith Fitz-Gerald

Clinical Trials Initiative- Dr. Robert Kimberly

OSP- Debbie Graves

IRB- Adam McClintock

Job Ladder- Mark Marchant

Pharmacy Fee Structure- Christopher Chapleau

CBR - Ashley Knight Specht

OnCore- John Sandefur

i2b2- Matt Wyatt

TIN- Frannie Horn





SAVE THE DATES

Research Orientation: September 26, 2019 and November 21, 2019

Special Topics in Clinical Research/Research Seminar:

- October 3: CT.Gov Workshop: Reporting Results
- October 17: How to Write IRB Submissions
- November 12: The How To's With OSP Submissions WEST PAVILION
- November 21: HIPAA Texting and Email 101
- December 5: Self Help-Stress Management

Next Lunch and Learn: December 10, 2019

Questions on training, please email: CRSPtraining@uabmc.edu





How to Gain Access:

Monitor Access to EHR:

<https://www.uab.edu/medicine/ctao/investigators/monitor-access-to-ehr>

OnCore Information:

<https://www.uab.edu/ccts/research-commons/oncore/resources>

OnCore Access:

https://www.uab.edu/medicine/ctao/images/OnCore_ID_Request_Form_V4_10.pdf

PowerTrials:

powertrials@uabmc.edu

Contact: Alicia Martin-Gunter abmartin@uabmc.edu

Children's of Alabama:

<https://www.uab.edu/medicine/peds/resources/resources/training-resources/research-team-training>

CT.gov Registration and Result Reporting:

Denise McKenzie dhmckenzie@uabmc.edu or Dorothy Shaw dshaw@ped.s.uab.edu





Clinical Trials Initiative

*Robert P. Kimberly, MD
Senior Associate Dean
Center for Clinical and Translational Science*

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Overview: Clinical Trials Initiative

- **Identification / Recruitment of Trial Opportunities**
- **Clinical Trials Workforce Development**
- **Tools and Processes**
- **Participant Recruitment**
- **Finances and Close-out**





OSP Updates

Debbie Graves
OSP Training Coordinator

dggraves@uab.edu (205) 934-1408

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OSP/RBO Updates

- Alice Harding – Non-Profit Grants & Contracts Associate Director, OSP
- UAB Updated F&A Policy – effective October 1, 2019
- Upcoming Research Administration Forum (RAF)





Primary Changes to UAB F&A Policy

- Policy terminology updated to incorporate 2 CFR 200, more commonly known as Uniform Guidance
- Investigator-initiated clinical trials will be charged Other Sponsored Activities rate (currently 36% MTDC)
- Fee-for-Service Activities will be charged Organized Research Rate (48.5%)





Research Administration Forum (RAF)

- New meetings series held three times a year: October, January, May
- Research faculty and administrators can hear from central research offices (OSP, IRB, GCA, etc.) about best practices and hot topics
- Hosted by Research Administration Network Group (RANG)
- Inaugural forum – October 9, 2019
 - 2:00 – 3:30 PM
 - Spain Auditorium





IRB Updates & Current Events

CCTS Lunch & Learn

Adam J. McClintock | Director
Office of the Institutional Review Board

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What are they doing over at the IRB office?

1. Launched Personnel eForm in July 2019
2. Piloting a Comprehensive Staff Training & Development Program
3. Establishing Metrics & Baseline Data
4. Preparing for AAHRPP Reaccreditation
5. Recruiting for Open Positions
 - i. Training Coordinator
 - ii. Systems Analyst
 - iii. Receptionist





Updates on Clinical Trials Initiatives

Mark Marchant, MPH, MBA, CCRP
Director
Clinical Trials Administrative Office

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Career Ladder

- Pilot
 - O'Neal Comprehensive Cancer Center
 - February-April
- Phase I
 - Anesthesia, Civitan, CRSP, Dermatology, Emergency Medicine, Exercise Medicine, ICOS, Radiology
 - June/July
- Phase II
 - Neurosurgery, OB/GYN, Ophthalmology, Orthopedic Surgery, Otolaryngology, Pediatrics, Psychiatry, Rad/Onc, Surgery, Urology
 - July/August





Career Ladder

- Phase III
 - Arts & Sciences, Health Professions, Public Health, Optometry, Dentistry
 - August/September
- Phase IV
 - Department of Medicine
 - September/October
- Phase V
 - Genetics, Neurology, Pathology, Nursing
 - October/November





Career Ladder

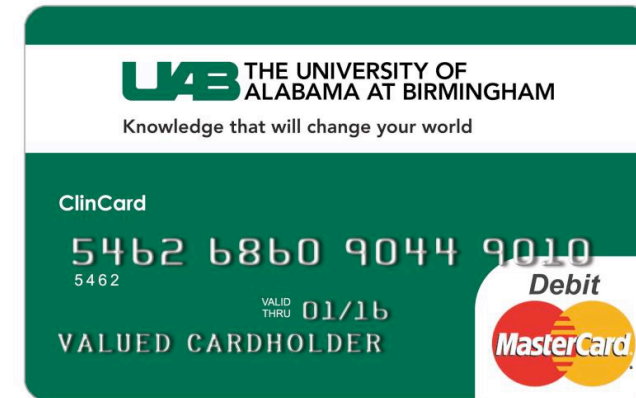
- Phase VI (Catch-up)
 - Any staff missed (new hires, transfers, etc.)
 - November/December
- Go-Live
 - Early 2020





Greenphire

- Pilot: Fall 2017
- Waves 1 & 2: 2018
- Wave 3: Q1/2 2019
- Wave 4: Q3 2019
- Wave 5: Q4 2019
 - Civitan, CCC, Orthopedic Surgery, Physical Medicine, Radiation Oncology, Dentistry, Nursing, Health Professions





Pending Accounts

- Initiated in January 2017 for industry-funded clinical trials
- Monthly reports to Award Managers of current accounts
- Expenses (especially PI effort) should be applied within 45 days of creation
- Going forward, contracts will be held by OSP until appropriate expenses applied





Research Summaries

- 1 page summary for treating physicians at point of care for participants in trials
- Created using standard template and emailed to powertrials@uabmc.edu
- Monthly report provided listing outstanding trials (6%)
- Must update OnCore if trial status changes to reflect in PowerTrials





Pharmacy Fee Structure

Christopher Chapleau
Manager, UAB Pharmacy Services

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New fee structure for Investigational Drug Services

Processing Fees

<input type="checkbox"/> Protocol Initiation	\$2,500 (once)
<input type="checkbox"/> Monthly Maintenance	\$50 (monthly)
<input type="checkbox"/> Study Closure	\$500 (once)
<input type="checkbox"/> Monitoring Visit	\$100 (each)
<input type="checkbox"/> Randomization Schema	\$250 (once)
<input type="checkbox"/> Storage (Room Temp)	\$100 (Monthly)
<input type="checkbox"/> Storage (< 8 Celsius)	\$300 (Monthly)
<input type="checkbox"/> Controlled Substance (CI-CII)	\$500 (Monthly)
<input type="checkbox"/> Controlled Sub. (CIII-CV)	\$200 (Monthly)
<input type="checkbox"/> After Hours Service	\$1000 (Monthly)
<input type="checkbox"/> Drug Destruction	\$100 (each)

Dispensing Fees

<input type="checkbox"/> Oral	\$30
<input type="checkbox"/> Intravenous (IV)	\$150
<input type="checkbox"/> Topical	\$30
<input type="checkbox"/> Extended IV Compounding	\$250
<input type="checkbox"/> Over-Encapsulation	\$ 1 per capsule
<input type="checkbox"/> Paper Documentation	\$25 per form
<input type="checkbox"/> After-Hours	\$200 (each)
<input type="checkbox"/> IVRS assignment	\$25 (each)
<input type="checkbox"/> Barcoding/Unit Dosing	\$1 (each)
<input type="checkbox"/> Patient Kit Creation	\$10
<input type="checkbox"/> Delivery Fee	\$10

Distribution Center

<input type="checkbox"/> Central Distributor Fee	\$500 (Monthly)
<input type="checkbox"/> Shipment - Room Temperature	\$75 + Actual Shipping+ Supply Cost
<input type="checkbox"/> Shipment – Refrigerated (non-monitored)	\$150 + Actual Shipping +Supply Cost
<input type="checkbox"/> Shipment – Refrigerated (Monitored)	\$250 + Actual Shipping + Supply Cost
<input type="checkbox"/> Shipment – International	\$300 + Actual Shipping +Supply Cost



Clinical Billing Review (CBR) Updates

Ashley Knight Specht

Manager, Clinical Billing Review

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Introductions – New CBR Staff

CBR Staff Updates

- **Dawn Matthews** - Retired in May of 2019
- **Ashley Specht** - Manager
- **Shameka Clark** - Clinical Research Analyst





CBR Annual Departmental Meetings

Annual Meetings

- **Goal** – An opportunity to build relationships between the CBR Analysts and the research departments we support, and to discuss department-specific information, provide training, and to provide updates on our process
- **Duration** – Meetings conducted September and October. Meetings should take around one hour (a little more if there are questions)
- **Location** - We will come to you (if you do not have a projector, we will bring copies of the slides)
- **Attendees** – FAP Submitters, but please invite additional research staff if you feel it would be beneficial
- **Information** - Copies of slides and additional information about our forms and process will be sent to you after the training is complete



- Submit to CBR for pricing
 - This is to obtain the CPT code costs of imaging
- Submit Radiology Quote Request form
 - Include Protocol and Imaging Manual
 - radresearch@uabmc.edu
 - This form is mandatory for all studies that have a Radiology clinical billable exam
 - This review ensures that the protocol is implemented within the various Radiology Departments
 - Additional costs will be quoted at this time also
 - Tech time, image transfer, etc.

UAB MEDICINE

RADIOLOGY Research Quote Request

Date Requested: _____

Study Title: _____

Short Study Name: _____ FAP #: _____

PI: _____

Nurse Coordinator: _____ Ext#: _____ Email: _____

Other Contact: _____ Ext#: _____ Email: _____

Location: TKC University Hosp Highlands Other: _____ # of Patients: _____

Sponsor: Federal Industry Cooperative Investigator Initiated Other _____

Metrics Required: Yes No _____

Please choose all that apply:

<input type="checkbox"/> Pre-site questionnaire	<input type="checkbox"/> Orderable Required	<input type="checkbox"/> Phantom	<input type="checkbox"/> Form Completion
<input type="checkbox"/> Site Initiation	<input type="checkbox"/> Tech/Radiologist Training	<input type="checkbox"/> Tech Time	<input type="checkbox"/> Special dictation

Clinical Imaging Services Summary: _____

CT _____

MRI _____

PET _____ NUC. MED. _____

DIAGNOSTIC _____ ULTRASOUND _____

Has a UAB Radiologist been consulted regarding this study? Yes No If so, whom? _____

Will a Radiologist receive effort from this study? Yes No If yes, whom? _____

Image Transfer Required: CD FTP Other _____

Please submit image transfer requests to: rimagetx@uabmc.edu

*** Non-routine research specific services (e.g., the completion of study forms, additional machine time, etc.) will be billed by Radiology Research. Routine services will be billed by the Health System.

Special Instructions: _____

Please submit this form with your FAP submission or send the form to radresearch@uabmc.edu.

UAB Radiology Research

Haley Hendrix

Brandi Barger

Amanda Richardson

radresearch@uabmc.edu

975-4559



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Data Quality Reports

John Sandefur, MBA, MSHI
Manager II-Application Architect
OnCore Team Leader

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What goes wrong with subject visits?

- If subjects are not taken off study or off treatment in OnCore and their subsequent visits are not Occurred, the visits remain in a status of Planned.
- If a visit is submitted by pressing the Submit and Close button and the radio button for Occurred is not chosen, the visit remains in a status of Marked as Planned.

Subject Visit Update	
Protocol No.: FIN-DEMONSTRATION-JS1	Protocol Status: OPEN TO
Subject MRN: 73483	Subject Name: PATIENT782005 FINI
Visit Details	
Visit Date	02/14/2018
Visit Status	<input checked="" type="radio"/> Planned <input type="radio"/> Occurred <input type="radio"/> Missed <input type="radio"/> N/A
Visit Description	
Data Collection Completed Date	
Monitored Date	
Collection Location	
Collection Time (hhmm)	





What happens when visits aren't occurred properly?

- It is important to recognize that CTBNs do not generate charges – they inform the billing offices what was planned and which accounts should receive the charges – the patient or research accounts.
- If visits are still in the Planned state, it may be that the subject status needs to be changed (and reflected in IMPACT), or it may be that the visits took place but were not occurred in OnCore. No one except the study team would know. A CTBN will not drop, so if charges drop from the Health System, they may be charged to the wrong payer – e.g. billed to the patient's insurance instead of to the study account.
- If visits are still Marked as Planned, it is likely that a CTBN should have dropped but did not since the visit was not marked as Occurred. Again, it is possible that charges may be billed incorrectly and mostly likely charged to the patient's account.
- When charges are billed incorrectly, we face compliance risk. If/when charges are denied by insurance, the Health System may have to write them off.





What happens when visits aren't occurred properly?

- Timeliness of Occurring visits is of utmost importance. To avoid issues with billing compliance visits must be occurred within 24-48 hours. If a visit is not marked as “Occurred”, a CTBN is not generated for use by the billing office. Without this timely CTBN there is a risk that charges will be billed incorrectly e.g. billed to the patient's insurance instead of to the study account.





What is the magnitude of this problem?

- Hundreds of visits were Planned and never Occurred over the last year.
- Hundreds more were left in the status of Marked as Planned.
- It is much more difficult to correct problems after the date of the visit!





The Subject Visit Details report

The screenshot shows the OnCore web application interface. At the top, there is a navigation bar with the OnCore logo and a menu icon. The menu items are: Admin, eCRFs/Calendars, Financials, Protocols, Reports, Subjects, and Specimens. The Reports menu is currently open, showing a dropdown menu with the following options: Accrual Monitoring, Jasper Reports Administration, Reports (highlighted), and Scheduled Reports. Below the navigation bar, there is a section titled "PC Console" with a question mark icon. This section contains several fields: Protocol No., Library:, Protocol Target Accrual:, RC Total Accrual Goal (Upper):, Accrual Monitoring, Sponsor:, Protocol Status:, and IRB Expiration:.

In the Subject Visits tab, you will find the Subject Visit Details report. This report will be run monthly by the OnCore Team and you will receive a copy by email, but you can run it at any time and stay current with your visits.

* Most roles in OnCore have permission to view this tab. If you cannot see it and want to view the report, give us a call.





The Subject Visit Details report - report filters

OnCore. Menu Admin eCRFs/Calendars Financials Protocols

Subject Visit Details

Criteria

Visit Date From (MM/DD/YYYY) 01/01/2019 Visit Date Thru (MM/DD/YYYY) 09/10/2019

Protocol No Type here to search

Procedure

Subject Staff (Last, First)

Organizational Unit Medical Center

Management Group YourManagementGroup Include in Results?

Visit Status Planned

Submit Clear Back

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OnCore. Menu Admin eCRFs/Calendars Financials Protocols

Subject Visit Details

Criteria

Visit Date From (MM/DD/YYYY) 01/01/2019 Visit Date Thru (MM/DD/YYYY) 09/10/2019

Protocol No Type here to search

Procedure

Subject Staff (Last, First)

Organizational Unit Medical Center

Management Group YourManagementGroup Include in Results?

Visit Status Marked As Planned

Submit Clear Back

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You will want to select a date range and your Organizational Unit and type in your Management Group. Then choose a visit status of Planned or Marked as Planned. You may also choose other filters.





The Subject Visit Details report - report output

Protocol No.	Subject MRN	Subj Name	Seq No.	Subject Inits	Visit Info	Visit Status	Earliest Visit Date	Latest Visit Date	Procedures	Footnotes	Forms	Subject Staff
Your Protocol	MRN	Smith, Jones		1 JS	02/20/2019 (Treatment (Every 3months): V4/12month)	Planned	02/20/2019	02/20/2019	Procedure list	Applicable footnotes		





Closing and abandoning trials

Closing and abandoning trials properly allows us to track active trials accurately. It is extremely important that we keep up with protocol (and subject) statuses!





Closing and abandoning trials - abandon

★ PC Console ?

Protocol No.: FINTEST2-JS Library: Medical PI: Sponsor:
Protocol Target Accrual: 10 Accrual To Date: 0 Protocol Status: **NEW**
RC Total Accrual Goal (Upper): 15 IRB Expiration:

Select Protocol

Main » Status Task Lists ClinicalTrials.gov

Treatment »

Institution

Accrual

Status »

Protocol Status History					
Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
07/29/2019	NEW				Sandefur,John

[On Hold](#) [Abandon](#)
[Update](#)

[CTRC Submission Form](#) |

Trials that have not been opened to accrual may be abandoned.





Closing and abandoning trials - closing

★ PC Console ?

Protocol No.: VALIDATION-JS1 Library: Medical PI: Maddox, William, R Sponsor: Pfizer Inc.
Protocol Target Accrual: 100 Accrual To Date: 1 Protocol Status: CLOSED TO ACCRUAL
RC Total Accrual Goal (Upper): 20 IRB Expiration: 01/01/2021

Select Protocol

Main »
Treatment »
Institution »
Accrual »
Status »
Reviews »
Documents/Info »

Status Task Lists ClinicalTrials.gov

Protocol Status History

Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
09/10/2019	CLOSED TO ACCRUAL	PI	Accrual goal met		Sandefur,John
01/01/2019	OPEN TO ACCRUAL				Bruer,Emily
01/01/2019	STUDY COORDINATOR SIGNOFF				Bruer,Emily
01/01/2019	IRB INITIAL APPROVAL				Bruer,Emily
07/09/2019	NEW				Bruer,Emily

[Undo Close To Accrual](#) [IRB Study Closure](#) [Terminate](#) [Open](#) [Update](#)

[CTRRC Submission Form](#)

Trials that have been opened to accrual and subsequently closed may be terminated or closed to the IRB.





QUESTIONS?

Call the HelpDesk at 4-8888

Email OnCore@uabmc.edu





Clinical Data & Tools to Support Research

i2b2 and the Enterprise Data Warehouse

Matt Wyatt

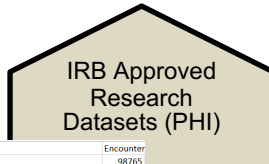
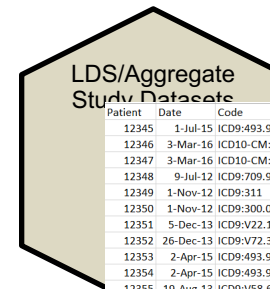
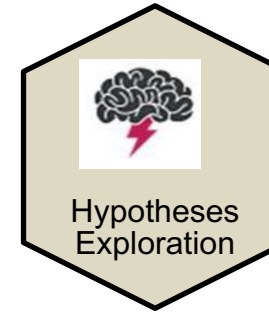
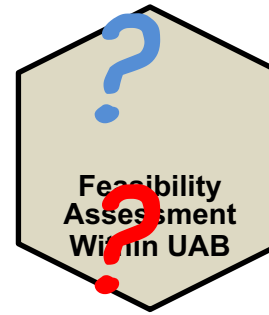
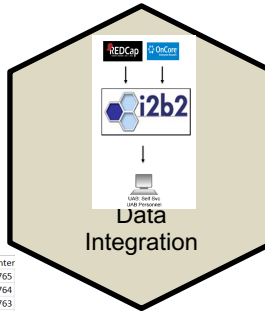
Director of Clinical Research Informatics
Center for Clinical and Translational Science
UAB Informatics Institute
Health System Enterprise Data Warehouse
mwyatt@uabmc.edu

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Support for All Parts of the Research Process

Patient	Date	Code	Concept Description	Encounter
12345	1-Jul-15	ICD9:493.90	Asthma	98765
12346	3-Mar-16	ICD10-CM:E78.5	Hyperlipidemia, unspecified	98764
12347	3-Mar-16	ICD10-CM:Z00.00	Encounter for general adult medical examination	98763
12348	9-Jul-12	ICD9:709.9	Dermatosis NOS	98762
12349	1-Nov-12	ICD9:311	DEPRESSIVE DISORDER, NOT ELSEWHERE CLAS	98761
12350	1-Nov-12	ICD9:300.02	Anxiety disorder, generalized	98760
12351	5-Dec-13	ICD9:V22.1	Prenatal care, normal, other pregnancy	98759
12352	26-Dec-13	ICD9:V72.31	Routine gynecological examination	98758
12353	2-Apr-15	ICD9:493.90	Asthma, unspecified	98757
12354	2-Apr-15	ICD9:493.90	Asthma	98756
12355	19-Aug-13	ICD9:V58.69	High risk medication use	98755
12356	22-Jan-16	ICD10-CM:J45.909	Unspecified asthma, uncomplicated	98754
12357	22-Jan-16	ICD10-CM:Z23	Encounter for immunization	98753
12358	22-Jan-16	ICD10-CM:I10	Essential (primary) hypertension	98752
12359	22-Jan-16	ICD10-CM:R73.01	Impaired fasting glucose	98751



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12359	22-Jan-16	ICD10-CM:R73.01	Impaired fasting glucose	98751

MRN	Last Name	First Name	Visit date	Location
12345	Patient	Fake	1-Jul-15	Your Clinic
12346	Patient	Fake	3-Mar-16	Another Clinic
12347	Patient	Fake	3-Mar-16	Your Clinic
12348	Patient	Fake	9-Jul-12	Your Clinic
12349	Patient	Fake	1-Nov-12	Your Clinic
12350	Patient	Fake	1-Nov-12	Another Clinic
12351	Patient	Fake	5-Dec-13	Your Clinic
12352	Patient	Fake	26-Dec-13	Your Clinic
12353	Patient	Fake	2-Apr-15	Your Clinic
12354	Patient	Fake	2-Apr-15	Another Clinic
12355	Patient	Fake	19-Aug-13	Your Clinic
12356	Patient	Fake	22-Jan-16	Your Clinic
12357	Patient	Fake	22-Jan-16	Your Clinic
12358	Patient	Fake	22-Jan-16	Another Clinic
12359	Patient	Fake	22-Jan-16	Your Clinic

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12345	1-Jul-15	ICD9:493.90	Asthma	98765
12346	3-Mar-16	ICD10-CM:E78.5	Hyperlipidemia, unspecified	98764
12347	3-Mar-16	ICD10-CM:Z00.00	Encounter for general adult medical examination	98763
12348	9-Jul-12	ICD9:709.9	Dermatosis NOS	98762
12349	1-Nov-12	ICD9:311	DEPRESSIVE DISORDER, NOT ELSEWHERE CLAS	98761
12350	1-Nov-12	ICD9:300.02	Anxiety disorder, generalized	98760
12351	5-Dec-13	ICD9:V22.1	Prenatal care, normal, other pregnancy	98759
12352	26-Dec-13	ICD9:V72.31	Routine gynecological examination	98758
12353	2-Apr-15	ICD9:493.90	Asthma, unspecified	98757
12354	2-Apr-15	ICD9:493.90	Asthma	98756
12355	19-Aug-13	ICD9:V58.69	High risk medication use	98755
12356	22-Jan-16	ICD10-CM:J45.909	Unspecified asthma, uncomplicated	98754
12357	22-Jan-16	ICD10-CM:Z23	Encounter for immunization	98753
12358	22-Jan-16	ICD10-CM:I10	Essential (primary) hypertension	98752
12359	22-Jan-16	ICD10-CM:R73.01	Impaired fasting glucose	98751





i2b2 Query/Analysis Tool

Project: UAB LDS (Early Fresh Data Load starting and 04-May-2016) User: MATTHEW WYATT

Search by Names Search by Codes

Find

Medications (Multum Ontology)

- proton pump inhibitors
 - dexlansoprazole - 3386
 - esomeprazole - 94153
 - lansoprazole - 7399
 - omeprazole - 65050
 - omeprazole-sodium bicarbonate - 1035
 - pantoprazole - 69107
 - rabeprazole - 1390

Query Name: Gastro--proton @10:10:46

Temporal Constraint: Treat all groups independently

Group 1: Gastro-esophageal reflux disease (ICD10:K21) - 37077

Group 2: proton pump inhibitors - 181615

Run Query Clear Print Query 2 Groups

Show Query Status Graph Results

Number of patients: 30170

For Query "Gastro--proton @10:10:46"

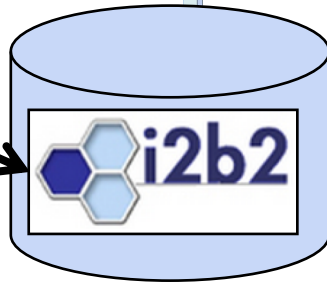
How to Get Data and/or Help?

What you can Ask?

What you can get!



Researcher



EDW Analysts

Enterprise Data Warehouse



Query Name: Your Query Name Goes Here

Temporal Constraint: Treat all groups independently

Group 1

Date From	Date To	Excluded?	Occurs X Times	Relevance %	Temporal Constraint
			> 0	100	Treat Independently

Group 2

Date From	Date To	Excluded?	Occurs X Times	Relevance %	Temporal Constraint
			> 0	100	Treat Independently

Group 3

Date From	Date To	Excluded?	Occurs X Times	Relevance %	Temporal Constraint
			> 0	100	Treat Independently

Group 4

Date From	Date To	Excluded?	Occurs X Times	Relevance %	Temporal Constraint
			> 0	100	Treat Independently

Finished Query: "Your Query Name Goes Here"

Compute Time: 52 secs

Number of patients for "Your Query Name Goes Here": patient_count = 3

Gender breakdown for "Your Query Name Goes Here":

- Female: 0
- Male: 0
- UNKNOWN: 0
- Unkznoss: 0
- UNSPECIFIED: 0

Vital Status patient breakdown for "Your Query Name Goes Here":

- Alive: 0
- Deceased: 0

Race patient breakdown for "Your Query Name Goes Here":

- American Indian or Alaska Native: 0
- Asian: 0
- Black or African American: 3
- Declined/Refuse: 0
- Hispanic or Latino: 0
- Middle: 0
- Native Hawaiian/Other Pacific Islander: 0

1	A	B	C	D	E	F	G	H	I
1	Patient Num	Encounter Number	Concept Code	Start Date	End Date	Text/Desc	Numeric	Units	
2	542822	1437307	ICD9:174.9	13-Feb-12	13-Feb-12	Breast cancer			
3	542822	3882648	SNMCT:4448450	6-Oct-12	6-Oct-12	Hypoglycemia			
4	542822	7214049	ICD9:174.9	6-Oct-12	6-Oct-12	Breast cancer			
5	542822	10843526	ICD9:441.7	26-Dec-14	26-Dec-14	Thoracoabdominal aneurysm, without mention of			
6	542822	2380775	ICD9:281.0	26-Dec-14	26-Dec-14	Pernicous anemia			
7	542822	2380775	ICD9:250.00	26-Dec-14	26-Dec-14	Type 2 diabetes mellitus without (mention of con			
8	542822	5007014	ICD9:782.1	11-Jan-13	11-Jan-13	Rash.			
9	542822	5314589	VITALS:BMI	21-Sep-12	21-Sep-12		26.26	kg/m ²	
10	542822	11428780	VITALS:BMI	27-Dec-14	27-Dec-14				
11	542822	10276801	UABLABS:31582	28-Dec-14	28-Dec-14				
12	542822	404417	UABLABS:31606	13-Feb-12	13-Feb-12				
13	542822	406870	UABLABS:31710	29-Jun-12	29-Jun-12				
14	542822	4318692	UABLABS:31606	26-Aug-12	26-Aug-12				
15	542822	3790992	UABLABS:31584	11-Jan-13	11-Jan-13				
16	542822	5007014	UABLABS:31787	2-Sep-12	2-Sep-12				
17	542822	3790992	UABLABS:31605	2-Sep-12	2-Sep-12				
18	542822	7576461	UABLABS:31587	2-Sep-12	2-Sep-12				
19	542822	404417	UABLABS:31701	8-Oct-12	8-Oct-12				
20	542822	5012603	UABLABS:31729	26-Dec-14	26-Dec-14				
21	542822	403278	UABLABS:31714	21-Sep-15	21-Sep-15				
22	542822	5012603	UABLABS:31658	2-Sep-12	2-Sep-12				
23	542822	2713170	UABLABS:31600	3-Sep-12	3-Sep-12				
24	542822	3824200	UABLABS:75282	7-Oct-12	7-Oct-12	Performance			
25	542822	3824200	UABLABS:31714	22-Sep-12	22-Sep-12				
26	542822	3882648	UABLABS:31609	3-Sep-12	3-Sep-12				
27	542822	3882648	UABLABS:69669	8-Sep-12	8-Sep-12				

```

Patient Num Encounter Number Concept Code Start Date End Date Text/Desc Numeric Units
542822 1437307 ICD9:174.9 13-Feb-12 13-Feb-12 Breast cancer
542822 3882648 SNMCT:4448450 6-Oct-12 6-Oct-12 Hypoglycemia
542822 7214049 ICD9:174.9 6-Oct-12 6-Oct-12 Breast cancer
542822 10843526 ICD9:441.7 26-Dec-14 26-Dec-14 Thoracoabdominal aneurysm, without mention of
542822 2380775 ICD9:281.0 26-Dec-14 26-Dec-14 Pernicious anemia
542822 2380775 ICD9:250.00 26-Dec-14 26-Dec-14 Type 2 diabetes mellitus without (mention of con
542822 5007014 ICD9:782.1 11-Jan-13 11-Jan-13 Rash.
542822 5314589 VITALS:BMI 21-Sep-12 21-Sep-12 26.26 kg/m^2
542822 11428780 VITALS:BMI 27-Dec-14 27-Dec-14
542822 10276801 UABLABS:31582 28-Dec-14 28-Dec-14
542822 404417 UABLABS:31606 13-Feb-12 13-Feb-12
542822 406870 UABLABS:31710 29-Jun-12 29-Jun-12
542822 4318692 UABLABS:31606 26-Aug-12 26-Aug-12
542822 3790992 UABLABS:31584 11-Jan-13 11-Jan-13
542822 5007014 UABLABS:31787 2-Sep-12 2-Sep-12
542822 3790992 UABLABS:31605 2-Sep-12 2-Sep-12
542822 7576461 UABLABS:31587 2-Sep-12 2-Sep-12
542822 404417 UABLABS:31701 8-Oct-12 8-Oct-12
542822 5012603 UABLABS:31729 26-Dec-14 26-Dec-14
542822 403278 UABLABS:31714 21-Sep-15 21-Sep-15
542822 5012603 UABLABS:31658 2-Sep-12 2-Sep-12
542822 2713170 UABLABS:31600 3-Sep-12 3-Sep-12
542822 3824200 UABLABS:75282 7-Oct-12 7-Oct-12 Performance
542822 3824200 UABLABS:31714 22-Sep-12 22-Sep-12
542822 3882648 UABLABS:31609 3-Sep-12 3-Sep-12
542822 3882648 UABLABS:69669 8-Sep-12 8-Sep-12
  
```





What's in i2b2?

Included Organizations:

- UAB Hospital, TKC, Highlands, WIC
 - i.e.. Anyone Using IMPACT

Organizations Not Included:

- CEFH, Children's, VA, CCTS Partners

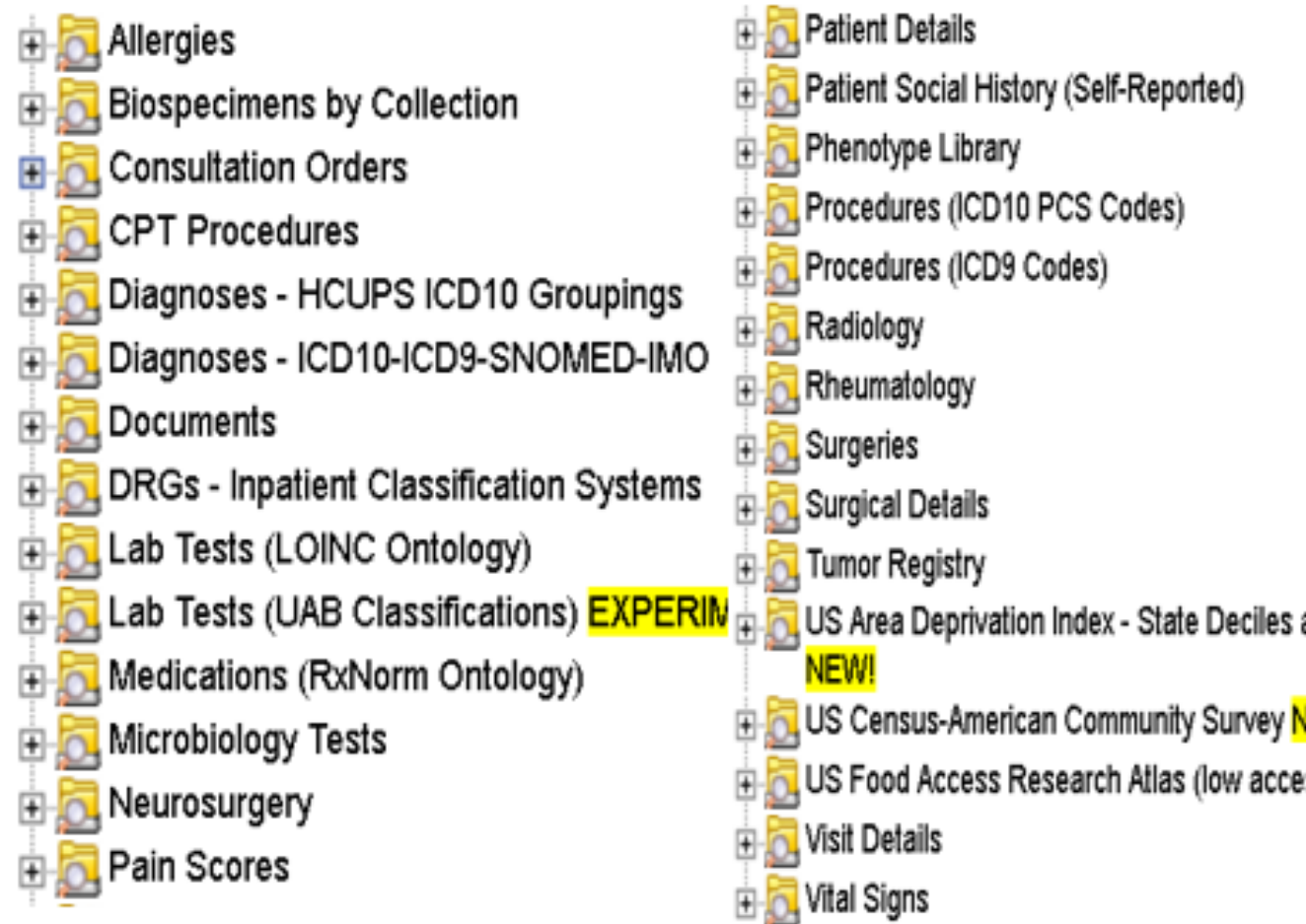
Amount of Data:

- ~ 1.07M Patients
- > 1Billion Facts

Major Systems Included:

- IMPACT, OnCore, Metriq, TransChart, TCBF, Census

Date Coverage: Generally, 2010/2011 - Present





More Information – Who to call

i2b2support@uabmc.edu or Google “UAB i2b2”

Informatics Services

- <http://www.uab.edu/ccts/research-commons/informatics>

EDW data requests

- <http://www.uab.edu/ccts/researchcommons/research-data-requests>

Information about i2b2

- <http://www.uab.edu/ccts/research-commons/informatics/i2b2>

i2b2 login URL: <https://i2b2-uab.hs.uab.edu>





Southeast Health Alliance for Research (SHARe) & Trial Innovation Network (TIN)

Jason Nichols, OD, MPH, PhD

CCTS Director- SHARe & TIN
Assoc. VP Research Engagement
& Partnerships
Office of Industry Engagement - OVPR

Frannie Horn, JD, EdS

CCTS Program Manager- SHARe & TIN
Office of Industry Engagement - OVPR

CENTER FOR CLINICAL & TRANSLATIONAL SCIENCE



SHARe

A 13-member consortium launched by the CCTS to build on the strength of our Partner Network to develop a truly transformational research enterprise in multisite studies for the Deep South.

<https://www.uab.edu/ccts/partnerships/share>





SHARe Partners

- AUBURN UNIVERSITY
- HUDSONALPHA INSTITUTE FOR BIOTECHNOLOGY
- LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER
- OCHSNER HEALTH SYSTEM
- OUR LADY OF THE LAKE REGIONAL MEDICAL CENTER
- PENNINGTON BIOMEDICAL RESEARCH CENTER
- SOUTHERN RESEARCH
- TULANE UNIVERSITY
- TUSKEGEE UNIVERSITY
- UNIVERSITY OF ALABAMA
- UNIVERSITY OF ALABAMA AT BIRMINGHAM
- UNIVERSITY OF MISSISSIPPI | UNIVERSITY OF MISSISSIPPI MEDICAL CENTER
- UNIVERSITY OF SOUTH ALABAMA





Why use SHARe?

- Multi-site trials frequently struggle to identify and enroll sufficient numbers of qualified participants.
- SHARe offers access to a large, regional and diverse population.
- SHARe can help you find a cohort that meets your criteria.
- SHARe resources are available at no cost to the project.





How does SHARe work?

Governance

- Governed by an Advisory Committee that meets once a month (second Tuesday at 12:00CT)
- Duties of Advisory Committee:
 - General oversight over all activities and operations of SHARe
 - Adopt and maintain Standard Operating Procedures (SOPs)
 - Accept or Deny proposed SHARe trials and projects
- Each Partner has a Partner Network Clinical Lead (PNCL) and one other representative





How does SHARe work?

Submission Process

- Fact Sheet about project is submitted by PI's office
- Circulated to and considered by Partners
- Interested Partners propose a site PI to SHARe administrator who connects sites with Lead PI team
- SHARe can assist with:
 - Single IRB through SMART IRB
 - Each institution has its' own processes and procedures for accepting responsibility or ceding review
 - Contract Templates
 - Staff Training

SHARe Request Form



Examples of Current SHARe Trials

- A Phase II Study of Cabozantinib for Recurrent or Persistent Cervical Cancer (USA Health)
- Antihypertensive Therapy for Mild Chronic Hypertension during Pregnancy: A Pragmatic Multicenter Randomized Trial (CHAP Trial) (UAB)
- Infant Formula Growth Study (Pennington Biomedical Research Center)
- A Randomized, Double-blind, Phase 2, Placebo Controlled Study to Determine the Safety and Efficacy of Ivacaftor (VX-770) for the Treatment of COPD (TOPIC Trial)(UAB)



How does UAB successfully engage SHARe?

Early Identification

of proposals, applications, project ideas!

Contact Frannie Horn at the CCTS

fhorn@uab.edu - 934-3980

<https://www.uab.edu/ccts/partnerships/share>





Trial Innovation Network

A new national collaborative initiative within the CTSA Program and is composed of three key organizational partners – the CTSA Program Hubs, the Trial Innovation Centers (TICs), and the Recruitment Innovation Center (RIC).

How Can We Help You?

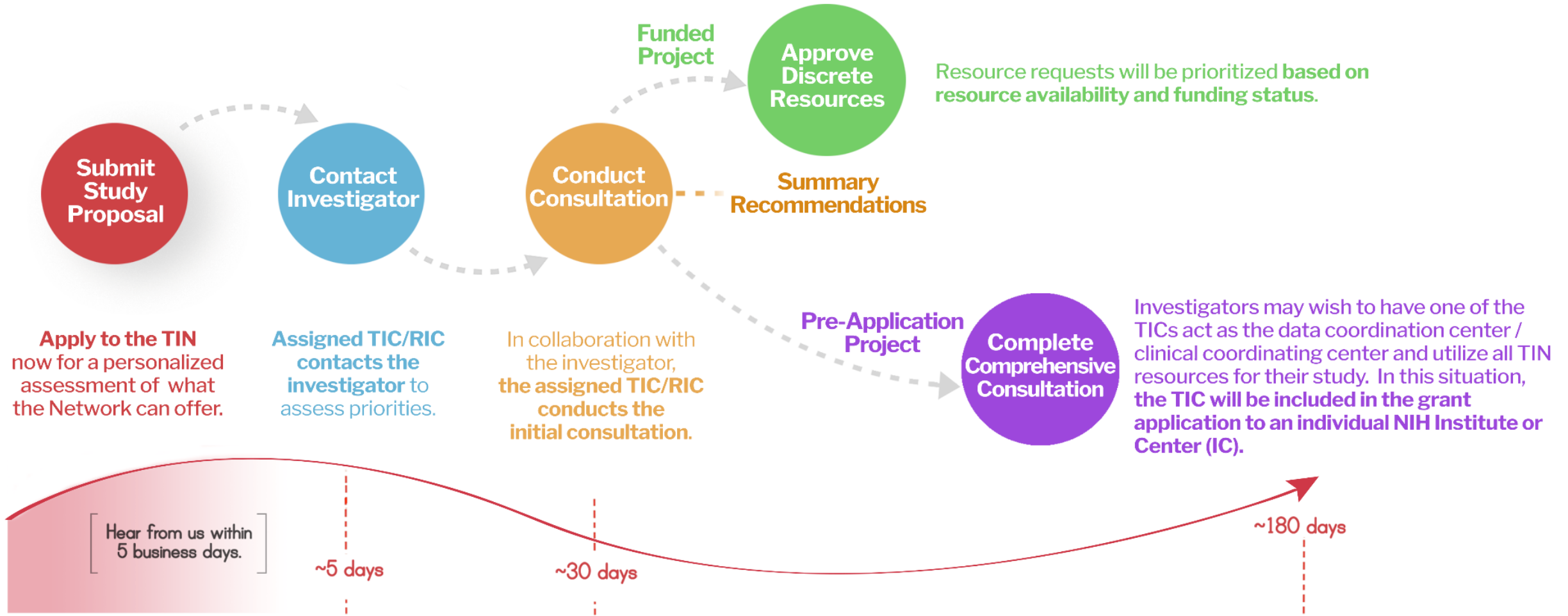


1. The Trial Innovation Network offers study investigators of multi-site trials the ability to request an **initial consultation or specific resources for a trial**, whether funded or in the planning stages.
2. Prior to submitting a Trial Innovation Network Project Proposal, study investigators must first **discuss the proposal with his/her CTSA Liaison** team and receive approval from the CTSA Program Hub Principal Investigator.
3. Once a study investigator submits a proposal, the proposal undergoes a series of reviews which can possibly lead to **Trial Innovation Network infrastructure and resources** to support your trial.

Questions? Contact your Frannie Horn at (205) - 934-3980. Learn more at trialinnovationnetwork.org

The Trial Innovation Network is supported by the National Center for Advancing Translational Sciences, National Institutes of Health, under award numbers U24TR001608, U24TR001597, U24TR001609, and U24TR001579.

Using the Trial Innovation Network to Plan Your Trial



Illustrated timeline is approximate and may be subject to change based on the responsiveness and needs of the research team and current number of active proposals





How does UAB successfully engage the TIN?

Early Identification

of proposals, applications, project ideas!

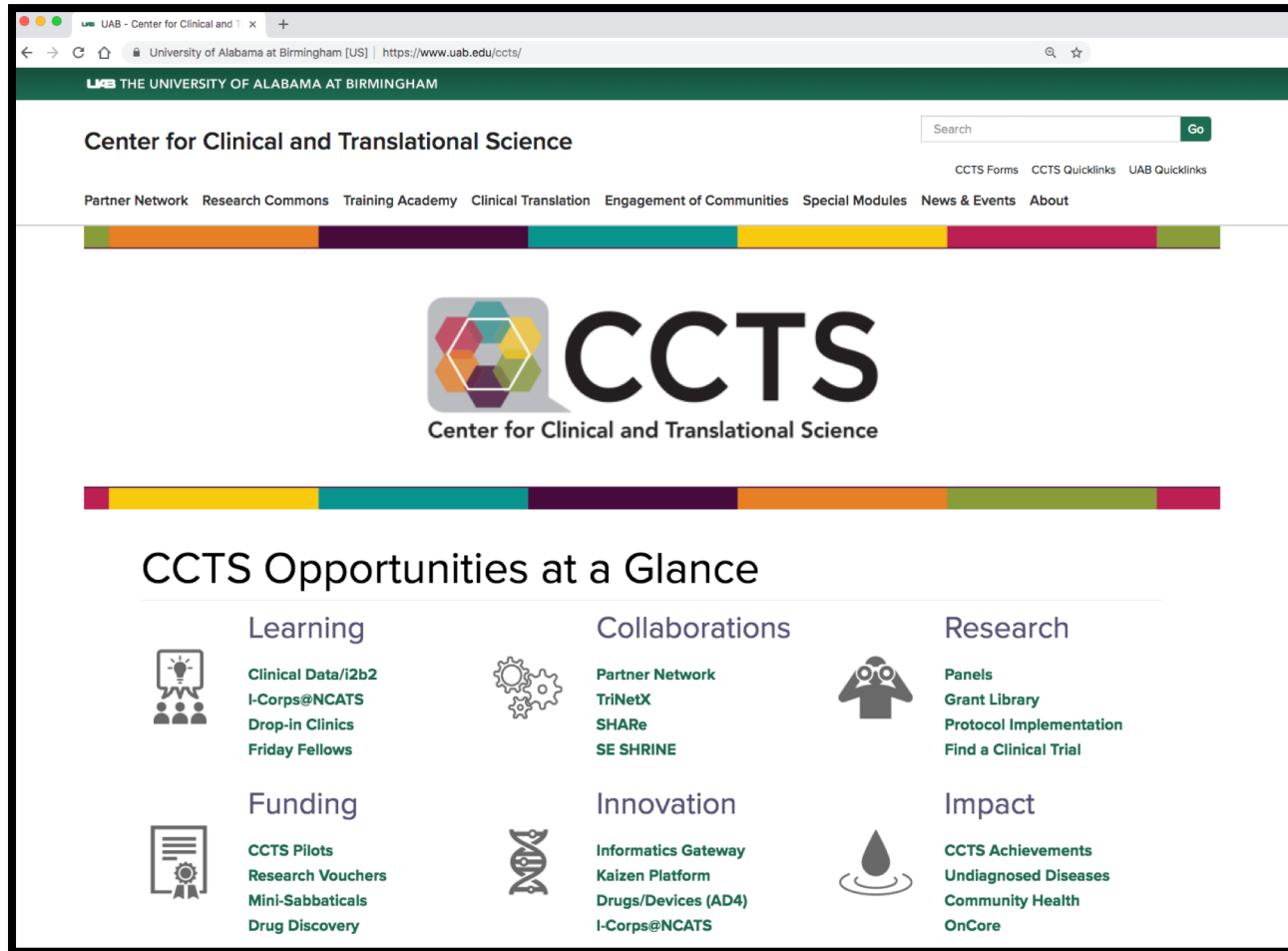
Contact Frannie Horn at the CCTS

fhorn@uab.edu – 934-3980

<https://www.trialinnovationnetwork.org>



Stay Connected



www.uab.edu/ccts



205-934-7442



ccts@uab.edu



PCAMS – 1924 7th Ave South



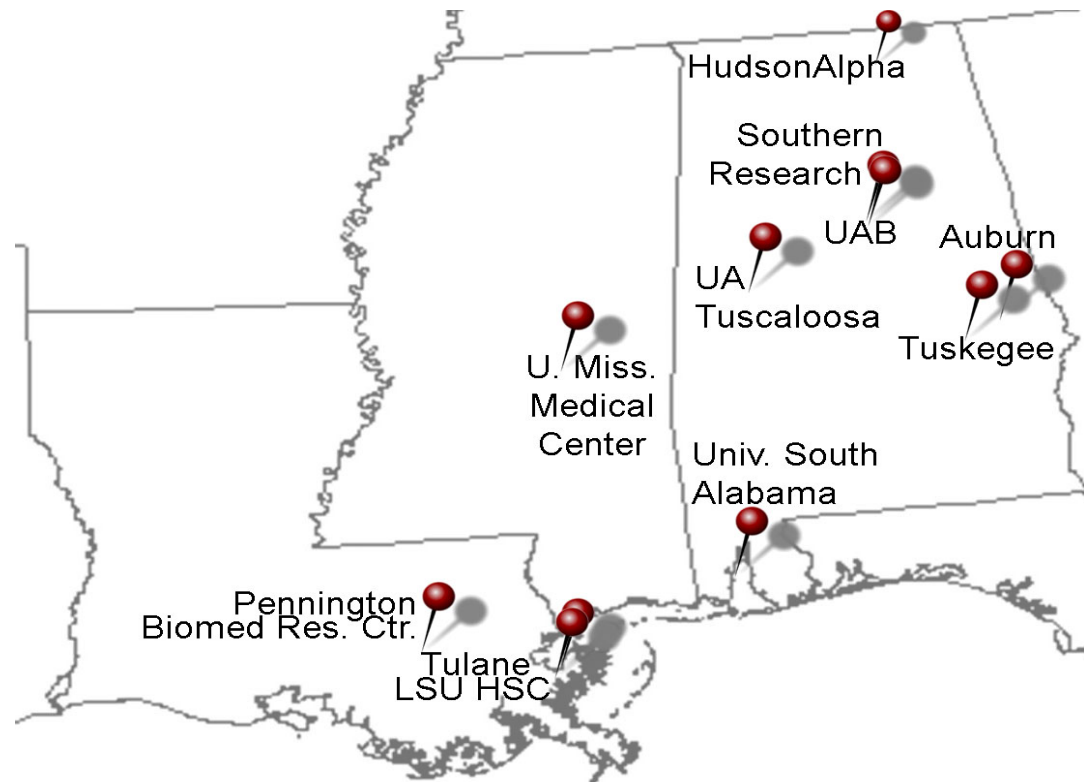
[@cctsnetwork](https://twitter.com/cctsnetwork)



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

Science through Synergy

Questions & Discussion



Next Lunch and Learn December 10, 2019

