



COORDINATING CENTER
— FOR CLINICAL TRIALS —

Coordinating Center for Clinical Trials (CCCT)

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Today's Discussion

Coordinating Centers

- Types of CCs and their services
- Why are they important to research

CCCT- Who we are

- Our services
- Our goal
- How can we collaborate

Center for Biostatistics Collaboration and Data Services

Center for Spatial-Temporal Modeling for Applications in Population Sciences



What are **coordinating** centers

-
- Mostly* utilized in multicenter trials (2+ enrolling centers)
 - Serve as the nucleus of large clinical research programs
 - Coordinate various activities and services needed for trial success
 - Play a huge role in communication among stakeholders
 - Some are founded in academic centers, others in industry
 - Typically charged with setting a milestone driven timeline and promoting a strategy that ensures the trial completes on time and on budget

Data Coordinating Centers (DCC)



As the name suggests, **DCCs** play more of a role on **activities associated with data** analysis and statistical design

- Expertise in clinical trial design and conduct (includes structure and quality standards)
- Collaborates in protocol development (statistical design, sample size calculations, analysis strategy)
- Provides data management and analyses
- Provides site selection based on feasibility/availability of data
- Insures appropriate adverse event monitoring (quality assurance)
- Procurement of services related to core labs (standardized data)
- Clinical monitoring of data (source comparison to database)
- Website support and online resources for the trial (EDC)
- Manuscript generation and dissemination of results

Clinical Coordinating Centers (CCC)



Similar in name, CCCs play more of a role on clinical activities

- Provide technical expertise in the disease area
- Developing protocol, consents, SOPs
- Contracting with clinical centers
- Formulate site performance plans and recruitment activity
- Develop content of data collection forms
- Coordinate regulatory approval activities
- Obtaining investigational study drug
- Training of sites on clinical protocols

Well-established groups can be both DCC and CCC

Academic Research Organizations (ARO)



-
- ❑ Have been around since 1980s
 - ❑ A university-based organization/or nonprofit institution that performs one or more functions in a research initiative
 - ❑ **AROs** provide
 - Academic expertise and leadership
 - Full-service clinical trial management capabilities
 - Site monitoring, safety monitoring, and clinical events classification
 - Data management, statistical analysis
 - ❑ The focus of **AROs**
 - Developing and sharing knowledge to improve patient care
 - Leading and conducting multicenter clinical trials
 - Ensuring these trial findings are published and presented



How are coordinating centers important to research

Successful trials require a team effort

- Sponsor/funding agency
- Investigators/clinical centers
- Vendors/partners/core labs
- Data Safety Monitoring Boards
- Participants

Challenges of Investigators

- Competing demands for your time
- Need for a central hub for logistics & communication
- Need for sound design and statistical analysis plan
- Need for data quality measures (standardization, monitoring)
- Provision of training (protocol, operations, EDC)



COORDINATING CENTER
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Coordinating Center for Clinical Trials (CCCT)





CCCT Mission and History

To improve a broad-spectrum of public health interests through the coordination of clinical trials, collaboration with clinical investigators, and development of statistical and trial methodology

- ❑ Founded in **1971**; ~\$250 million in **funded projects**
- ❑ **Many large** NIH & Industry multi-center clinical trials
- ❑ Phase I, II, III trials (from **32** to **42,000** patients and site management ranging from **1** to **600+** sites)
- ❑ Leading role in clinical trials research (**science and practice – 5 Fellows of Society for Clinical Trials**)
- ❑ Long history of **collaboration** with many academic and community institutions

Major Trials



- ❑ **HDFP** (Hypertension Detection and Follow-up Program)
- ❑ **BHAT** (Beta-Blocker Heart Attack Trial)
- ❑ **SHEP** (Systolic Hypertension in the Elderly Program)
- ❑ **ALLHAT** (Antihypertensive and Lipid-lowering Treatment to Prevent Heart Attack Trial); **GenHAT** (Genetics of ALLHAT)
- ❑ **SAVE** (Survival and Ventricular Enlargement Trial)
- ❑ **CARE** (Cholesterol and Recurrent Events Trial)
- ❑ **CCTRN** (Cardiovascular Cell Therapy Research Network)
- ❑ **CRYO-ROP** (Cryotherapy for Retinopathy of Prematurity)
- ❑ **ETROP** (Early Treatment of Retinopathy of Prematurity)
- ❑ **FLAT-SUGAR** (FLuctuATion with inSULin and Glp-1 Added together)
- ❑ **TWITCH** (TCD with Transfusions Changing to Hydroxyurea)
- ❑ **Mobile stroke unit trial** (Comparative effectiveness study in tPA eligible stroke patients)
- ❑ **CHILD** (Autologous Cardiac Stem Cell Injection in Patients with Hypoplastic Left Heart Syndrome (HLHS): An Open Label Pilot Study)
- ❑ **ELPIS II** (Allogeneic Human Mesenchymal Stem Cell (MSC) Injection in Patients with HLHS)
- ❑ **DCM II** (Comparative Efficacy and Safety of Transendocardial Injection of Allogeneic-MSC in Patients with Non-Ischemic Dilated Cardiomyopathy)

Impact



Intellectual Contribution

- ❑ 600+ publications, 70,000+ citations
- ❑ 2002 ALLHAT JAMA paper , ISI Web of Science “one of the most cited recent papers in the field of Clinical Medicine”, H-index ~ 100
- ❑ Trials published in NEJM, JAMA, Lancet and other leading journals

Landmark trials

- ❑ Changed worldwide treatment of hypertension
- ❑ Major impact on preventing blindness in premature infants
- ❑ Changed practice of post-MI treatment

Clinical Care

- ❑ Findings noted in clinical guidelines by national health organizations (e.g. – JNC 5-8); reviews; educational materials
- ❑ Findings resulted in standard of care for a disease

Our Services



Study Design

- We help Investigators with design in all phases of trials
- Design includes hypothesis development, well-defined study objectives, selection of study outcome measures and an appropriate assessment schedule, power analysis, and sample size estimations
- Designs include comparative effectiveness, parallel group, factorial, cluster, cross-over, non-inferiority, futility, seamless Phase II-III, SMART, MOST, etc.



Our Services

Study Implementation

- Site selection and recruitment of qualified Investigators and centers
- Assistance with protocol development and trial related training materials (e.g. core lab materials, CRFs, manuals of operation, etc.)
- Creation of secure web-based data entry system allowing Investigators 24/7 access to their clinical site performance metrics and quality control reports
- Recruitment and participation rate assistance: development of recruitment aids (video, posters, cards, etc.), study newsletters, and other trial promotion materials
- Safety and regulatory oversight (AE monitoring, reporting for FDA, DSMB, IRB)

Our Services



Data Analysis and Dissemination

- ❑ CCCT uses best-practice methods for the analysis of clinical trial data. Novel statistical methods have also been developed to deal with more complex data when standard methods cannot be used
- ❑ Specific expertise in prognostic and prediction models/algorithms using machine learning
- ❑ Leadership in preparation of scientific reports and manuscripts and in the publication and presentation of study findings and results

Our Services



Trial Support

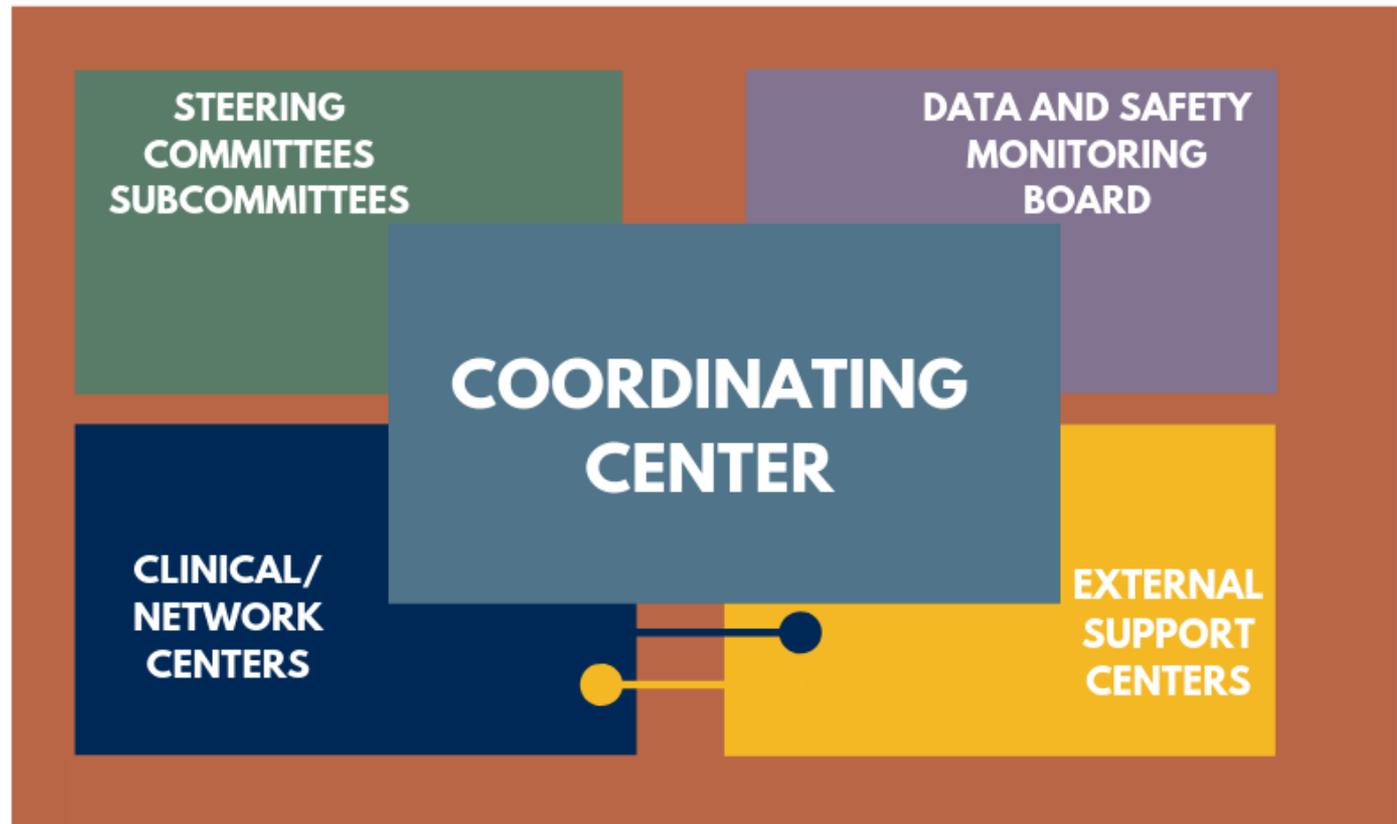
- ❑ Integrated approach combines administrative support, with project management, data programming, and statistical expertise from seasoned personnel to provide leadership and collaboration for the operation of a first-class coordinating center
- ❑ Design and development of web-based applications for data collection and randomization.
- ❑ Execution of plan for central data acquisition, harmonization, management, and analysis, including patient randomization and quality control measures
- ❑ Management of the fiscal and budgetary affairs of clinical trial operations; including subcontracts for patient care expenses to clinical centers and core laboratories

Clinical Trial Services & Structure

SPONSOR

Services

- Randomization
- Clinic/ppt. Recruitment
- Staff Training & Certification
- Quality Control
- Site Management
- Biostats
- Protocol Development
- Programming
- Data Collection & Mgmt.
- Dissemination
- Regulatory/Safety
- Contracts & Payments
- Site Monitoring



CCCT Team-Faculty



Primary affiliation

- Jose-Miguel Yamal
- Dejian Lai
- Ruosha Li
- Michael Swartz
- Luis Leon Novelo
- Vahed Maroufy
- Lara Simpson
- Evan Kwiatkowski

Secondary affiliation

- Shreela Sharma
- Irene Tami-Maury

CCCT Team - Staff



Grants and Contracts Specialist

- Kevin Banks
- Joy de la Rosa

Project management team

- Dr. Kiran Mansoor
- Cristina Coronel
- Doug Merkitch
- Mahrukh Jamil

Database and software developer team

- Gina DeWildt
- Mike Gonzalez
- Binu Lal
- Alphonsa Devasia

Clinical Data Monitor

- Cristina Coronel

Biostatistician

- Mengxi Wang
- Brian Heckler
- Jing Ning
- Faruk Hussain

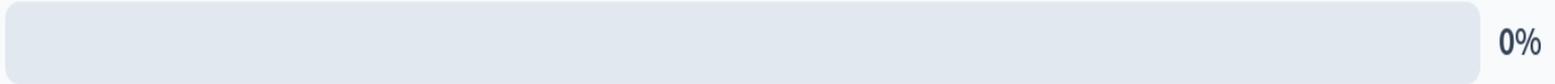
Current Studies (with coordination)

1. BEST MSU study (Jose-Miguel Yamal)
2. VIRTUAL trial (Yamal)
3. CATCH Healthy Smiles study (Yamal, Shreela Sharma)
4. Food Rx Trials – HHS Phase 2 (Yamal, Sharma)
5. Food Rx Trials – HHS Phase 3 (Yamal, Sharma)
6. Food Rx Trials – EHF (Yamal, Sharma)
7. Food Rx Trials – AHA RENEW Pilot (Sharrief, Sharma, Yamal)
8. Food Rx Trials – AHA MANGO Pilot (Sharma, Ranjit, Yamal)
9. Food Rx Trials – AboutFresh (Sharma, Ranjit, Yamal)
10. Food Rx Trials – SmallPlaces (Sharma, Ranjit, Yamal)
11. NoNO Trial (Yamal)
12. GAMBIT (Yamal, Luis Leon Novelo)
13. Multiple Sclerosis Implementation Network (MSIN) (Fernandez, Yamal)
14. CHILD trial (Dejian Lai)
15. ELPIS trial (Lai)
16. DCMII trial (Lai)
17. HVIP (Ruosha Li)
18. MultiStem[®] trial (Michael Swartz)
19. TROOP (Stacia DeSantis)
20. BioTROOP (DeSantis)
21. POSTCare-O: Survivorship Care for Women Living with Ovarian Cancer (Ghosh)
22. Texas Cares (Swartz, DeSantis)
23. Texas Firefighter Cancer Study (TFCS, Lai)

*Names in parentheses are CCCT Leads

I plan on conducting a pilot or small clinical trial in the next 5 years.

Yes



0%

No



0%

I plan on conducting a multi-site trial in the next 5 years.

Yes



0%

No



0%



COORDINATING CENTER
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Contact us:

Jose-Miguel.Yamal@uth.tmc.edu

Website:

<https://sph.uth.edu/research/centers/ccct/>

Center for Biostatistics Collaboration and Data Services

Center for Biostatistics Collaboration and Data Services

Mission and goals

- Integrate and coordinate our expertise and resources to provide support/services to biomedical and health science research
 - biostatistics, informatics, and computational expertise
- Promote the use and awareness of cutting-edge biostatistics and data science approaches in biomedical and health science research and practice;
- Provide training to statisticians, computational experts, and data scientists
 - To communicate and collaborate with biomedical and health scientists

Who we serve

- Clinical, biomedical and health science investigators from
 - Research institutions and Academic organizations
 - Medical centers, research or teaching hospitals,
 - And similar organizations at UTHealth and TMC;
- Industrial partners or users within our scope of services and support

Services and expertise

Biostatistics consulting and data analysis services

- Study design and sample size/power calculation
- Development of statistical components and analysis plan for grant applications
- Statistical data analysis and assistance with manuscript preparations
- Statistical data visualization analysis with proper interpretation
- Preliminarily analyze and explore data for grant applications
- Statistical Genetics and Bioinformatics, including “omics” data
- EHR/EMR and other healthcare data integration and analytics
- Imaging and Wearable device stream data analysis and modeling

Data management services

- Perform data management, data extraction, data integration, and data preparation
- Support experimental design for new data collection
- Support data sharing
- Use AI, data science, machine learning, natural language processing tools and methods in data analysis and grant applications

Policies and charges

Small grants (NIH R21 and R03 or K-award)

- Minimum effort of 5% for all years for a faculty service provider

Regular NIH R01

- Suggested effort is 10-15% for a faculty service provider

Large program or center grants,

- 10-20% of the overall project budget is suggested for data management, modeling, and analysis, which depends on the size and complexity of collected data from the project.

For non-grant application services

- The flat rate is \$175 per person/hour for academic investigators.
- Appropriate authorship or ownership should be honored (mutual agreement)

The first consultation session is Free for a new project

More details

Details on Areas of expertise and services

<https://sph.uth.edu/dept/bads/consulting-services>

How to Collaborate with Us:

- Email us with a brief description of your project and needs.
- We'll schedule a free consultation meeting to discuss your project and suggest a faculty member with matched expertise.

Contact: Dr. Ruosha Li
Ruosha.Li@uth.tmc.edu

**Center for Spatial-temporal Modeling
for Applications in Population Sciences
(CSMAPS)**

CENTER FOR SPATIAL-TEMPORAL MODELING FOR APPLICATIONS IN POPULATION SCIENCES (CSMAPS)



Center Founding Director

Cici Bauer, PhD cici.x.bauer@uth.tmc.edu
Associate Professor
James W. Rockwell Professorship in Public Health
(Preventive Medicine and Epidemiology)
Department of Biostatistics and Data Science
School of Public Health
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Center Administrator

Porsha V. Day, MPA porsha.vallo@uth.tmc.edu
CSMAPS
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School of Public Health
University of Texas Health Science at Houston

CSMAPS Mission and Vision:

- pioneer the development and application of cutting-edge **spatial-temporal data science**, to enrich our understanding of population health dynamics.
- make complex data and analyses accessible to support informed public health policy-making.
- bolster the understanding and use of spatial-temporal modeling techniques among researchers, practitioners, and decision-makers through targeted capacity-building initiatives.

CPRIT Core Facility (TEX-SIM) Expertise

Texas Spatial-Temporal Data Science, Informatics, and Modeling Core (**TEX-SIM**) core facility, funded by CPRIT in 2025.

Bioinformatics and Data Linkage Services

- Link individual-level (e.g., patients) data (e.g., electronic health records, surveys) with TEX-SIM curated community-level datasets (e.g., social determinants of health, environmental exposures, access to healthcare)

Spatial-Temporal Data and Modeling Services

- Spatial-temporal modeling, small area estimation, multilevel models, and simulation studies

Population Epidemiology Services

- Epidemiology study design and methods, environmental health, environmental factors, and health disparities

Dashboard and Visualization

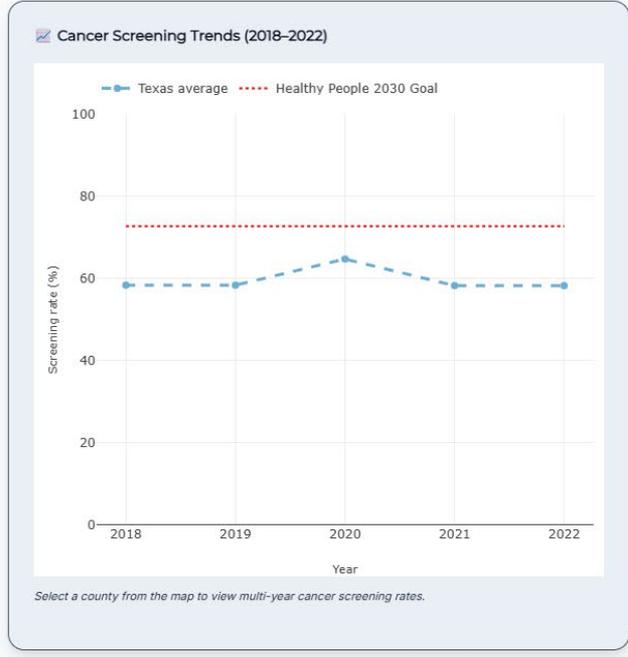
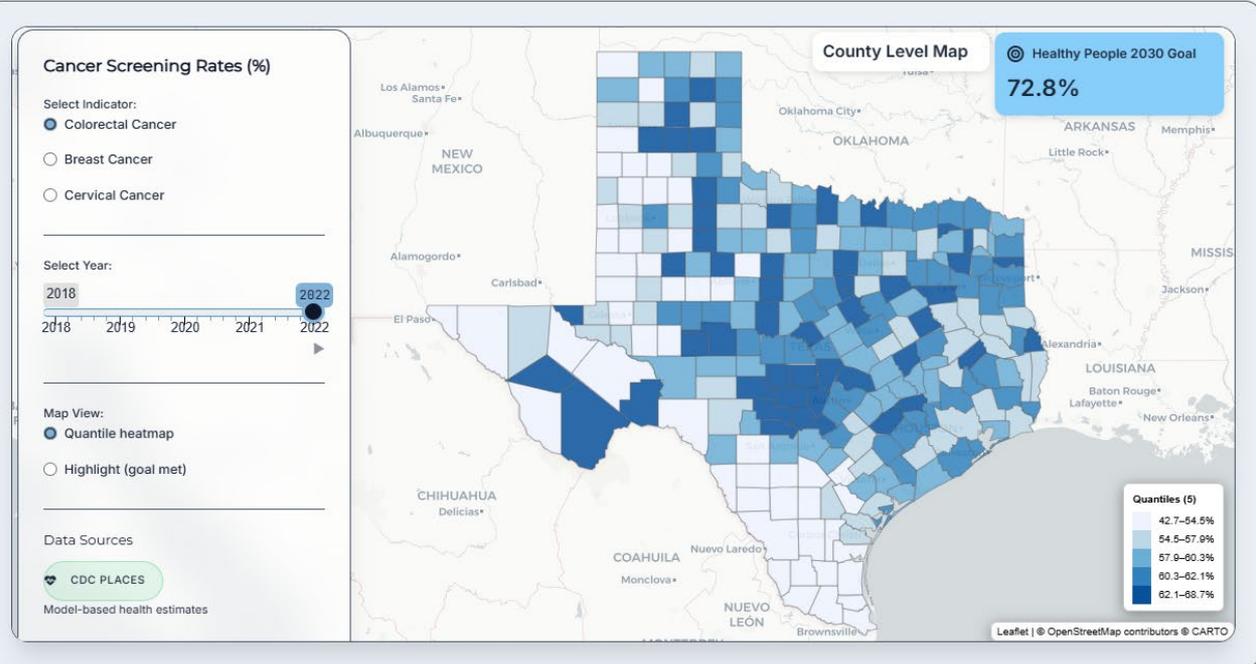
- User-friendly dashboards, analysis reports, and visualizations

Community Profiles Dashboard: InsightTX

go.uth.edu/InsightTX

- InsightTX
- Texas Cancer Screening
- Social Determinants
- Health Indicators
- Environmental
- Spatial Accessibility
- Community Selection Design
- Texas Chronic Disease Burden
- About

TEXAS CANCER SCREENING RATES



Developed by TEX-SIM Core Facility; supported by CPRIT Grant [RP250630](#)

Learn more about TEX-SIM

Visit go.uth.edu/TEX-SIM to learn more about the team and services available.

For interest and/or service inquiries, please complete our TEX-SIM Intake Survey Form at [go.uth.edu/TEX-SIM Intake](https://go.uth.edu/TEX-SIM_Intake).

Interact with the InsightTX dashboard to explore cancer screening disparities at the community level through real-time data visualization at go.uth.edu/InsightTX.



go.uth.edu/TEX-SIM

Summary

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- Center for Biostatistics Collaboration and Data Services
- Center for Spatial-Temporal Modeling for Applications in Population Sciences