Coordinating Center for Clinical Trials (CCCT)

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Today's Discussion

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- 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)

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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)

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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)

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- 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

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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)

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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

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- **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

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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

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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

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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

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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

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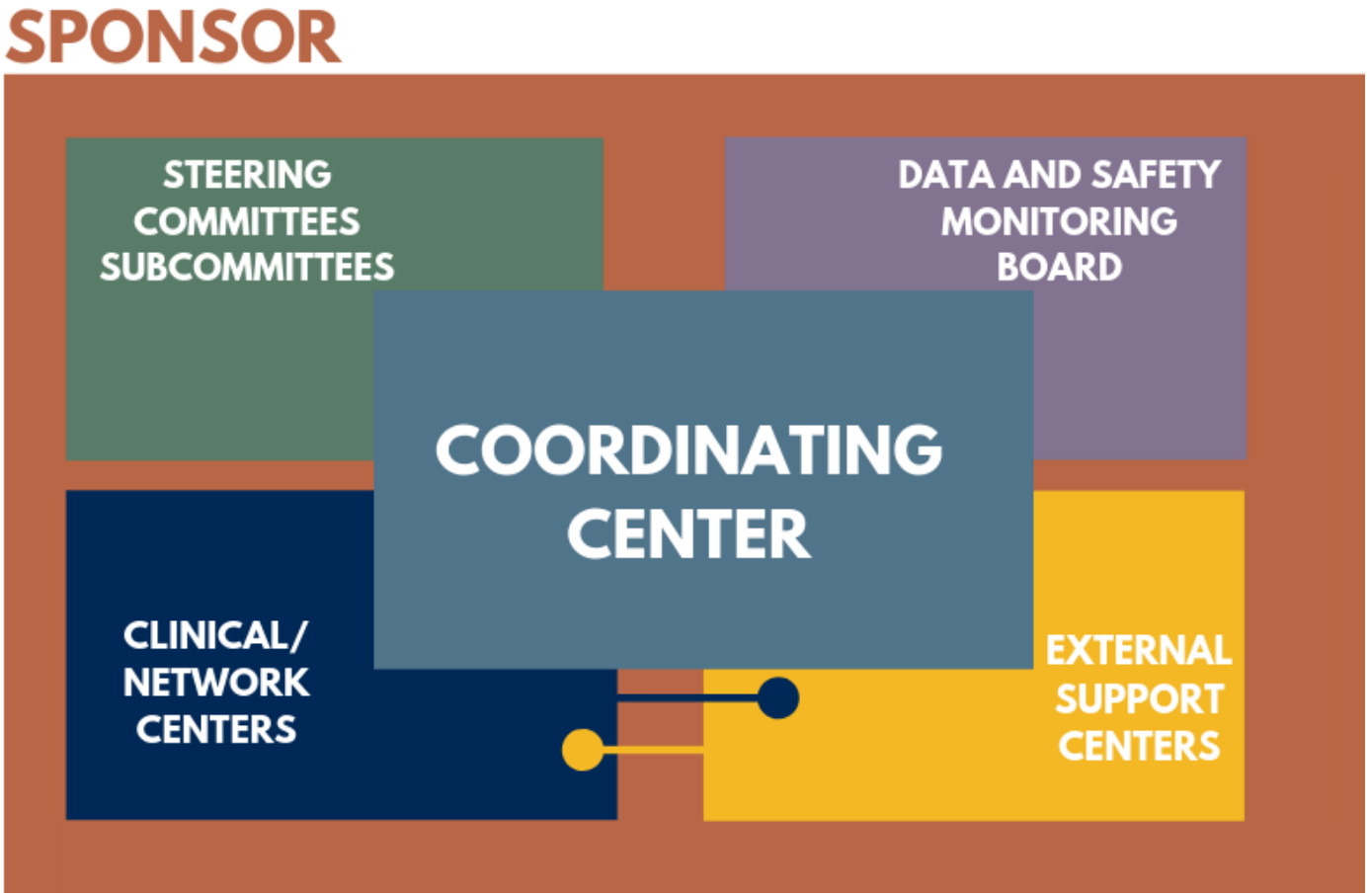
Trial Support

- 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

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

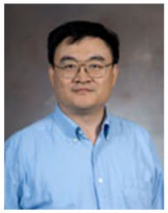


CCCT Team-Faculty

COORDINATING CENTER FOR CLINICAL TRIALS

Jose-Miguel Yamal, PhD
Coordinating Center Director
Professor of Biostatistics

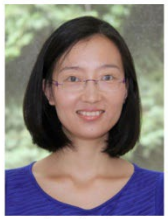
Samiran Ghosh, PhD
Professor & Vice Chair
Biostatistics



Dejian Lai, PhD
Professor
Biostatistics

Stacia DeSantis, PhD
Professor
Biostatistics

Shreela Sharma, PhD
Professor
Epidemiology, Human Genetics, & Environmental Sciences



Ruosha Li, PhD
Associate Professor
Biostatistics

Michael Swartz, PhD
Associate Professor
Biostatistics

Luis Leon Novelo, PhD
Assistant Professor
Biostatistics

Vahed Maroufy, PhD
Assistant Professor
Biostatistics

Irene Tami-Maury, DrPH
Assistant Professor
Epidemiology, Human Genetics & Environmental Sciences

Evan Kwiatkowski, PhD
Assistant Professor
Biostatistics

Lara Simpson, PhD
Faculty Associate
Biostatistics

Project Management and Trial Support Teams

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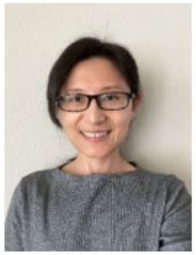
Charlie Coton, MS
Manager Sys Analyst Srvcs

Gina DeWildt
Programmer Analyst IV

Michael Gonzalez
Programmer Analyst III

Kiran Mansoor, MD
Research Coordinator III

Sibi Mathew, MS
Clinical Research Associate



Mengxi Wang, PhD
Biostatistician

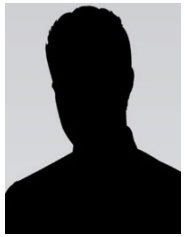
Brian Heckler, MS
Biostatistician

Journey Martinez, MS
Biostatistician

Jing Xie, MS
Biostatistician

Staci Hinojosa
Grants & Contracts Specialist

Mahrukh Jamil, MSc
Clinical Research Coordinator III



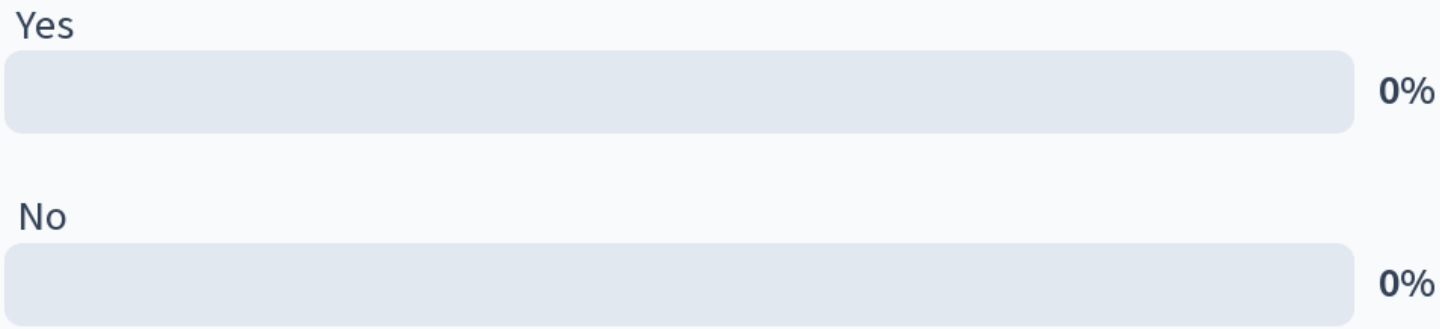
Angela Bowling

Clinical Trial Program Manager

>$16million in current funded projects (over grant lifespan)

1. BEST MSU study (Jose-Miguel Yamal)
2. VIRTUAL trial (Yamal)
3. CATCH Healthy Smiles study (Yamal)
4. Food Rx Trials - HHS (Yamal)
5. Food Rx Trials – EHF (Yamal)
6. Food Rx Trials – TCHP (Yamal)
7. GAMBIT (Yamal, Luis Leon Novelo)
8. Multiple Sclerosis Implementation Network (MSIN) (Samiran Ghosh, Yamal)
9. CHILD trial (Dejian Lai)
10. ELPIS trial (Lai)
11. DCMII trial (Lai)
12. MultiStem® trial (Michael Swartz)
13. TROOP (Stacia DeSantis)
14. BioTROOP (DeSantis)
15. POSTCare-O: Survivorship Care for Women Living with Ovarian Cancer (Ghosh)
16. Texas Cares (Swartz, DeSantis)
17. HVIP (Ruosha Li)
18. NoNO Trial (Yamal)

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



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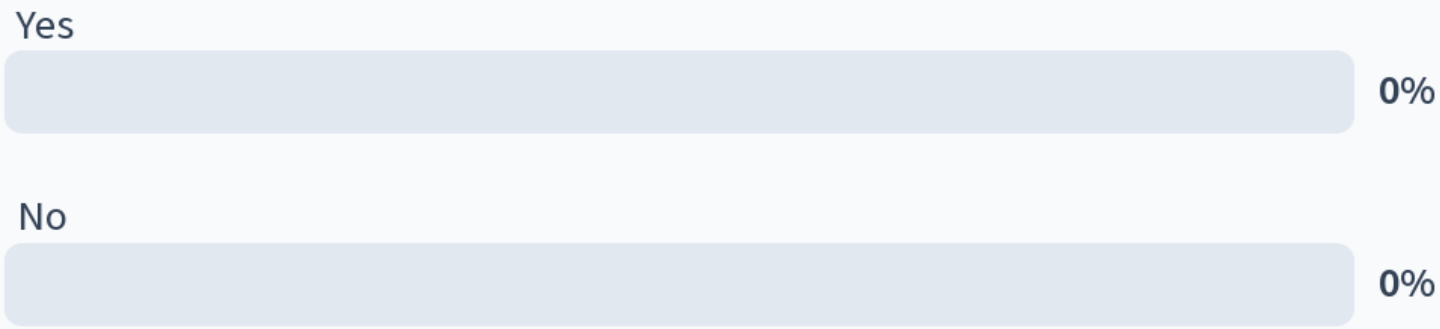
I plan on conducting a multi-site trial in the next 5 years.



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COORDINATING CENTER
FOR CLINICAL TRIALS

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
- Statistical data visualization analysis with proper interpretation
- Bioinformatics (“omics”) data analysis
- EHR/EMR and other healthcare data integration and analytics
- Imaging and Wearable device stream data analysis and modeling
- Complex data visualization

Data management services

- Identifying public data, Data extraction, sharing,
- Support experiment design data collection and sharing and management

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 the

- minimum effort is 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 advising session is Free for a new project

More details

Details on Areas of expertise and services

https://sph.uth.edu/research/centers/cbcds/

Contact:

Dr. Vahed Maroufy
vahed.maroufy@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)

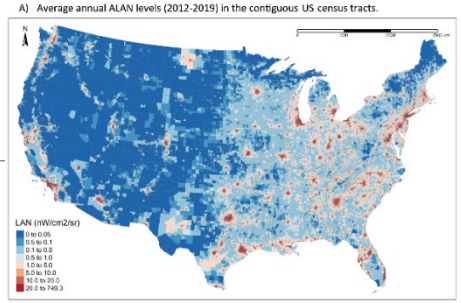
Center Founding Director
Cici Bauer, PhD cici.x.bauer@uth.tmc.edu
Associate Professor
James W. Rockwell Professorship in Public Health
(Preventive Medicine and Epidemiology)
Department of Biostatistics and Data Science
School of Public Health
University of Texas Health Science at Houston

Center Administrator
Porsha V. Day, MPA porsha.vallo@uth.tmc.edu
CSMAPS
Department of Biostatistics and Data Science
School of Public Health
University of Texas Health Science at Houston

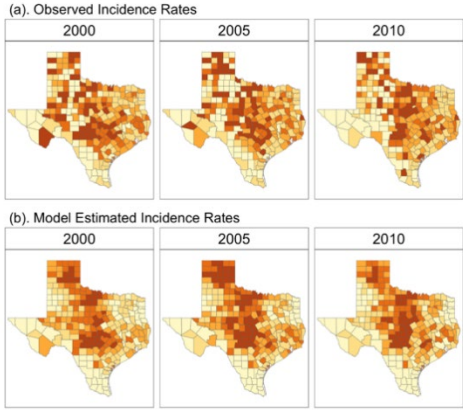
CSMAPS Mission and Vision:

- 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.

Current Projects

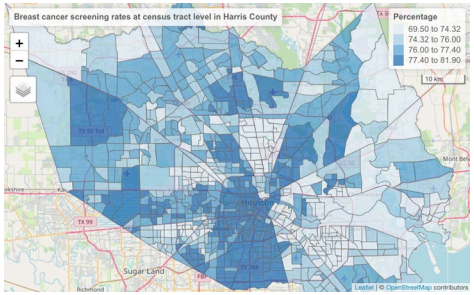


- Cancer Prevention and Place-based Intervention (CPRIT)
- Predict to Prevent: Dynamic Spatiotemporal Analyses of Opioid Overdose to Guide Pre-emptive Public Health Responses (NIH R01)
- Bayesian Spatiotemporal for COVID-related Outcomes (e.g., small area estimation community-based interventions, wastewater surveillance)
- Apply NASA's Earth Observation Product to Improve Artificial Light at Night Mappin and Public Health Surveillance, and Environmental Justice (NASA)
- Circadian Rhythms using Wearable Devices with Bayesian Hidden Markov Models (NIH)
- Bayesian Learning for Spatial Point Processes and Graphic Models (NSF)
- many others …



Center website https://sph.uth.edu/research/centers/csmaps/

Contact us!



Summary

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