

# CCCT SERVICES

Physician Investigators are busy people. Let us help coordinate your research effort. We'll work with you from design to dissemination to meet all of your trial needs.



**COORDINATING CENTER**  
— FOR CLINICAL TRIALS —

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## STUDY DESIGN

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- 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.
- Our statistical designs include comparative effectiveness, parallel group, factorial, cluster, cross-over, non-inferiority, futility, seamless Phase II-III, SMART, MOST, etc.

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## STUDY IMPLEMENTATION

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- Let us help you with site selection and recruitment of qualified Investigators and centers.
- We'll work with you to develop protocols and trial related training materials (including core lab materials, case report forms, manuals of operation, etc.).
- CCCT employs a secure web-based data entry system allowing Investigators 24/7 access to their clinical site performance metrics and quality control reports.
- Our center serves as a central resource to retain high recruitment and participation rates by providing recruitment aids (video, posters, cards, etc.), study newsletters, and other trial promotion materials.
- We provide safety and regulatory oversight (adverse event monitoring, reporting for FDA, DSMB, IRB).

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## DATA ANALYSIS AND DISSEMINATION

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- 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.
- We have specific expertise in prognostic and prediction models/algorithms using machine learning.
- We exhibit leadership in preparation of scientific reports and manuscripts and in the publication and presentation of study findings and results.

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## TRIAL SUPPORT

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- Our 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. We are the communication hub for your teams.
- Our programmers design and develop web-based applications for data collection and randomization. The team executes plans for central data acquisition, harmonization, management, and analysis, including patient randomization and quality control measures.
- We also manage the fiscal and budgetary affairs of clinical trial operations; including subcontracts for patient care expenses to clinical centers and core laboratories.