# Biostatistics Scope of Work Agreement

## General Information

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| **Investigator** | Miranda Kroehl [Miranda.Kroehl@ucdenver.edu](mailto:Miranda.Kroehl@ucdenver.edu) | **Date** | September 17, 2018 |
| **Project Number** | P3Kroehl |  |  |
| **Project Title** | Efficacy and safety of twice- vs once-daily dosing of lisinopril | | |

## Project Cost and Milestones

**Project Type:** Average Data Analysis/Publication

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| **Billing Phase and Milestone** | **Cost** |
| **Phase 1: Project Start Up** Discuss and review project materials, establish timelines, deliverables, and data structures with biostatistician. | $ 450 |
| **Phase 2: Exploratory Analysis** Establish preliminary analysis dataset, run descriptive statistics and graphics, and create a report. | $ 3525 |
| **Phase 3: Comprehensive Analysis** Complete comprehensive analysis and present a report. Additional changes to analysis are anticipated and part of the Project Complete phase. | $ 3525 |
| **Phase 4: Project Complete** Complete final analysis and publication quality figures. | $ 450 |
| **Customization:** | 0 |
| **Total Due** | **$ 7950** |

## Understanding of Project

### Project Description

Cardiovascular disease (CVD) is the leading cause of death in the United States, and hypertension is a major modifiable risk factor for this disease. Of adults with hypertension, approximately 75% are on some sort of anti-hypertensive, and 50% of those still have uncontrolled blood pressure (BP). Generally, patients are prescribed once-daily medication at a standard dose. If their BP is still not controlled after 8 weeks on this regimen, the dose is increased, and their BP is checked again after another 8 weeks. However, many of the standard anti-hypertensives have relatively short half lives and may be more effective if taken twice daily instead of once daily. The investigators aim to examine the safety and efficacy of a twice daily dose of lisinopril compared to a once daily dose (with the same total daily dose).

### Timelines/Deadlines

* Abstract Deadline: Tuesday, September 25, 2018

### Study Design

Data were pulled retrospectively from EHRs, and participants were selected based on whether they had been prescribed an increased dose of lisinopril (going from 20 mg to 40 mg). This cohort was then split up based on whether they were prescribed the increased dose once daily or twice daily, which produced two groups of 45 patients. Patients on other medication known to affect blood pressure, or who had changes in their medication during the study were excluded.

Age, sex, race/ethnicity, and BMI were pulled from the EHR in addition to BP measurements, as these are potential covariates that need to be controlled for.

Serum creatinine and potassium are also included in the data, as a way of measuring the safety of the drug dosing regimen.

### Anticipated Sample Size

We anticipate 90 total participants, with 45 in the once daily group and 45 in the twice daily group.

### Descriptive Statistics Desired

A standard table 1, showing the demographics of the two groups. We will also include comparisons of BP measurements before and after the dose increase for both groups. Change in BP will be compared in terms of raw change (mmHg), and proportion of patients achieving BP control based on the latest clinical guidelines.

### Hypothesis

**Primary**

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| **Hypothesis** | The twice-daily group will demonstrate a greater improvement in BP compared to the once-daily group. |
| **Outcome(s)** | The change in blood pressure (systolic and diastolic) between the two groups |
| **Explanatory Variable** | SBP and DBP |

**Secondary**

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| **Hypothesis** | The twice-daily group will have lower or less of an increase in serum creatinine and potassium compared to the once-daily group. |
| **Outcome(s)** | Change in serum creatinine and potassium between the two groups |
| **Explanatory Variable** | Creatinine and Potassium |

**Tertiary**

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| **Hypothesis** | More twice-daily patients will achieve BP control. |
| **Outcome(s)** | Number of patients in each group below optimal BP cut points (130/90). |
| **Explanatory Variable** | SBP and DBP |

### Additional Notes

**Approval of Agreement**

By approving this Scope of Work Agreement, you are acknowledging that you have read and agree to the project costs and milestones, timelines, project details, and terms and conditions outlined in this document.

**To approve this Scope of Work Agreement click the button below.**

**Approve Scope of Work Agreement ⏵**[**https://forms.ucdenver.edu/secure/cida\_biostatistics\_consulting\_sow\_approval**](https://forms.ucdenver.edu/secure/cida_biostatistics_consulting_sow_approval)

(If you don’t agree with this Scope of Work Agreement or would like to withdraw your request for CIDA services, please send us an email to [cida@ucdenver.edu](mailto:cida@ucdenver.edu?subject=Don't%20Agree%20with%20CIDA%20Scope%20of%20Work%20Agreement) with a brief explanation.)

## Terms and Conditions

### Clean data requirements - ready for analysis

The data are assumed to be cleaned and ready for analyses unless otherwise agreed upon, and a data dictionary should be provided to the analyst. We strongly encourage the use of [REDCap](http://redcapinfo.ucdenver.edu/) as a data collection and management tool.

### Report writing, abstract and manuscript preparation and revision

A final report will be created with an introduction, statistical methods, and results section. These sections will be close to publication ready. The CIDA biostatistician will edit the methods and results section for publication and read the final version of the manuscript prior to submission. Assuming the biostatistician has provided significant contribution to the manuscript in terms of performing analyses and contributing to the results and methods sections, the biostatistician shall be a co-author on the publication, acknowledging the intellectual contribution of the work.

Assuming no substantial new analysis is needed, the CIDA biostatistician will assist with writing a response to reviewer’s statistical questions, make revisions to the paper and review the final version of any revised manuscript. If substantial new analysis is required, a new scope of work will be created and with costs agreed upon by both parties.

### CIDA Authorship Guidelines

The CIDA abides by the [International Committee of Medical Journal Editors (ICMJE) guidelines concerning authorship](http://www.icmje.org/). Visit our CIDA website to learn more about [CIDA’s authorship policies](http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/CBC/Biostatistics-Consulting/Pages/authorship.aspx).

**Specific CIDA guidelines include:**

* The biostatistician performing the analysis will be a co-author on the publication to acknowledge the intellectual contribution to the work. Statistician co-authors will use their primary appointment affiliation on manuscripts and abstracts.
* To maintain study and statistical integrity, data collected for publication and abstracts will only be analyzed after study completion.
* The CIDA biostatistician performs the analysis, collaborates in the structuring of the presentation of the results, and writes the "statistical methods" section of the paper.
* The biostatistician reviews the publication and any revisions prior to submission.
* The biostatistician will assist with revisions, keeping in mind your revision deadlines.

### CIDA’s right to cancel or close out a project

Please approve the Scope of Work (SOW) within 15 days (or prior to anticipated start of work, if less). SOWs not approved within 30 days will be closed. Projects which remain inactive for over 60 days will be closed unless prior arrangements have been made, and a final bill will be sent for work completed.

### CCTSI subsidized projects

If the project cost is subsidized by the Colorado Clinical and Translational Sciences Institute (CCTSI), you are required to cite the CCTSI grant in posters and publications. Please review the [CCTSI’s Citation and CTSA grant language](http://www.ucdenver.edu/research/CCTSI/about/Pages/Cite-Grant.aspx).