

## eMERGE Network: Manuscript Concept Sheet

Reference Number (to be assigned by CC)	NT401
Submission Date	7/15/2020
Project Title	An evaluation of statin and the severity among Individuals with COVID-19
Tentative Lead Investigator (first author)	TBD
Tentative Senior Author (last author)	Wei-Qi Wei
All Other Authors	Todd Edwards, Josh Peterson, Digna Velez Edwards, Dan Roden
Sites Participating	Open to all sites Current participants: Vanderbilt
Background / Significance	<p>Since January 2020, novel coronavirus has spread to nearly every country and territory in the world. As of 04/27/2020, more than 3 million COVID -19 cases have been confirmed throughout the United States. Accumulated evidence suggests that intense inflammation, blood clots, and stroke are some of the most severe symptoms of COVID-19. Statins are not only the first-line drug of lowering cholesterol. They also decrease inflammation, reduce blood clots, prevent damage to endothelial tissue, and may act as antivirals.</p>
Outline of Project	<p>A recent study reported statin treatment during a hospital stay is associated with improved mortality rates among hospitalized COVID-19 patients. We will explore if statin users have a decreased likelihood of developing severe outcomes of COVID-19.</p> <p>We defined hospitalization as the marker for severity. We will also evaluate the feasibility of implementing the WHO multi-level definition of respiratory severity (i.e., (1) normal / not in the hospital, (2) in the hospital requiring oxygen by simple nose cannula or mask, (3) in the hospital requiring more advanced support like a pressurized mask or "high-flow" oxygen device, (4) requiring a mechanical ventilator, (5) Dead).</p> <p>The study cohort will include all individuals either being confirmed COVID-19 positive by a SARS-CoV-2 PCR test or had a COVID-19 ICD10 code (U07.1) after April 1<sup>st</sup>. We will define cases as statin users while controls as non-statin users.</p> <p>We will conduct a logistic regression to compare the severity between cases and controls. We will adjust our results by age, gender, race, observation length in EHR, and other confounding indications for admission.</p>

<b>Desired Data - Common Variables*</b> <i>(Available from the CC)</i>	<input checked="" type="checkbox"/> Demographics <input checked="" type="checkbox"/> ICD9/10 codes <input type="checkbox"/> CPT codes <input checked="" type="checkbox"/> Phecodes <input checked="" type="checkbox"/> BMI <input type="checkbox"/> Common Variable Labs <input type="checkbox"/> Common Variable Meds <input type="checkbox"/> Other: Case/Control status on Phase I and <input type="checkbox"/> Phase II phenotypes
<b>Other Desired Data</b> <i>(Available from participating sites)</i>	<b>COVID</b> outcomes such as hospitalization, pneumonia, admission and time in ICU, intubation and time intubated, death, supplemental oxygen, and other related outcomes.
<b>Desired Genetic Data</b>	<input type="checkbox"/> eMERGE I-III Merged set (HRC imputed, GWAS) <input type="checkbox"/> eMERGE PGx/PGRNseq data set <input type="checkbox"/> eMERGEseq data set (Phase III) <input type="checkbox"/> eMERGE Whole Genome sequencing data set <input type="checkbox"/> eMERGE Exome chip data set <input type="checkbox"/> eMERGE Whole Exome sequencing data set <input type="checkbox"/> Other (not listed above):
<b>Does project pertain to an existing eMERGE Phenotype?</b>	<input checked="" type="checkbox"/> Yes, if so please list: Phecodes and other COVID outcomes <input type="checkbox"/> No
<b>Planned Statistical Analyses</b>	regression analysis
<b>Ethical Considerations</b>	None noted
<b>Target Journal</b>	Related clinical journal, e.g., circulation
<b>Milestones</b> <i>(This section should include the key dates for completion of project, including approval, project duration, draft completion, and submission.)</i>	<ol style="list-style-type: none"> <li>1. phenotype data collection from participating sites: by the end of 2020</li> <li>2. Conduct analysis: 2 months</li> <li>3. Result explanation and manuscript preparation: 2-3 months</li> </ol>