|  |
| --- |
| **eMERGE Network: Manuscript Concept Sheet** |
| **Reference Number** *(to be assigned by CC)* |  NT448 |
| **Submission Date** | 4/21/22 |
| **Project Title** | Designing a Comprehensive Education Program for Participants, Providers, and Research Teams: The eMERGE Consortium Experience  |
| **Tentative Lead Investigator** *(first author)* | John Connolly1 |
| **Tentative Lead Investigator Email Address**  | connollyj1@chop.edu  |
| **Tentative Senior Author** *(last author)* | Hakon Hakonarson1, Maya Sabatello4 |
| **eMERGE Site Sponsor & Contact** | The Children’s Hospital of Philadelphia  |
| **All Other Authors**  | Eta Berner2, Shannon Terek1, Sabrina Suckiel3, Julia Wynn4, Ingrid Holm5, Maureen Smith6, Dean Karavite1, Heide Aungst7, Kevin Dufendach7, Catrina Nelson7, Sue Bakken4, Wendy Chung4, others …  |
| **Sites Participating** | 1 CHOP2 UAB 3 Mount Sinai4 Columbia 5 BCH6 Northwestern7 CCHMCOthers… |
| **Background / Significance** | The success of the eMERGE program relies in large part on the generation, delivery and communication of polygenic risk scores (PRS) which, in addition to family history, clinical, and monogenic risk factors, have the potential to augment healthcare in adult and pediatric participants. The size, scope, and, particularly, novelty of the study necessitates development of a comprehensive and diverse suite of educational resources to address the needs of individuals from a range of backgrounds. This paper will summarize the consortium’s collective approach to 1) assessing and 2) developing educational approaches for its primary stakeholders – participants, providers, and study staff. To this end, the paper will summarize existing eMERGE 4 research activities focused on education and subsequently delineate how these approaches informed development of eMERGE resources.  |
| **Outline of Project** | First, the paper will review the wide range of eMERGE sub-projects, both at individual sites as well as network-wide initiatives, which address education needs of participants, providers, and/or study staff. This overlaps with work led by the ELSI, Education, Clinical Decision Support, and other groups, all of which identified educational needs among different constituent members of the Network. Second, the paper will discuss the development of core Education products of the eMERGE initiative, including a wide range of training material and formal/informal educational initiatives. Many of these products were formatively developed from research questions addressed early in the program and constitute a comprehensive and diverse catalog. Ultimately this paper aims to shed light on the challenges encountered and solutions provided by a largescale and novel clinical trial of this kind and aims to summarize lessons-learned for similarly ambitious programs.  |
| **Desired Data - Common Variables\*** *(Available from the CC)* | [x] Demographics [ ] ICD9/10 codes[ ] CPT codes[ ] Phecodes[ ] BMI | [ ] Common Variable Labs[ ] Common Variable Meds☐ Geocoding 2015 ACS variables[x] Other: Case/Control status  |
| **Other Desired Data *(Available from participating sites)*** | *Please specifically list out any data elements that participating sites would collect or extract from clinical or other sources for this project (i.e. not common variables above)* Description of local sites’ education sub-projects/activities will vary. Summary stats for relevant projects will be utilized.  |
| **Desired Genetic Data** | [ ] eMERGE I-III Merged set (HRC imputed, GWAS)[ ] eMERGE PGx/PGRNseq data set [ ] eMERGEseq data set (Phase III)[ ] eMERGE Whole Genome sequencing data set[ ] eMERGE Exome chip data set[ ] eMERGE Whole Exome sequencing data set[ ] Other (not listed above): |
| **Does project pertain to an existing eMERGE Phenotype?** | [ ] Yes, if so please list [x] No |
| **Planned Statistical Analyses** | Most likely descriptive statistics only |
| **Ethical Considerations** |  |
| **Available Funding or Resources** |  |
| **Target Journal** | Genetics in Medicine  |
| **Milestones***(This section should include the key dates for completion of project, including approval, project duration, draft completion, and submission.)* | May 31, 2022: Provisional layout October, 2022: Deadline for sites to submit summaries of respective projects from local sites November 30 2022: Draft 1 circulated among writing groupDecember 31, 2022: Manuscript submitted for review  |

**\*Common Variables available across all datasets:**

* Demographics: sex, year of birth, decade of birth, race, ethnicity
* Codes: (repeated values & age at event): ICD, CPT, Phecodes
* BMI: (repeated value & age at event) height, weight, BMI
* Labs: (lab name, repeated lab value & age at event) Serum total cholesterol, LDL, HDL, Triglycerides, Glucose fasting/non-fasting/unknown, & White Blood Cell count
* Medications: (medication name, repeated, & age at event) Cerivastatin sodium, Rosuvastatin, Simvastatin, Fluvastatin, Pravastatin, Lovastatin, Atorvastatin, & Pitavastatin
* Other: Case/Control status on Phase I and Phase II phenotype: only on GWAS dataset participants