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| **eMERGE Network: Proposal for Analysis**  Project/Manuscript Concept Sheet | |
| **Reference Number** | NT274 |
| **Submission Date** | 2/28/2018 |
| **Project Title** | Harmonization of Genomic Medicine Outcomes: Comparison of eMERGE Outcomes to ClinGen Actionability Working Group Evidence-based Summaries |
| **Tentative Lead Investigator** *(first author)* | Janet L. Williams, MS, LGC (Geisinger) |
| **Tentative Senior Author**  *(last author)* | Marc S. Williams, MD (Geisinger) |
| **All Other Authors** | TBD, open to network |
| **Sites Involved** | Geisinger, Vanderbilt (Coordinating Center), open to all network sites |
| **Background / Significance** | Genomic medicine is transitioning to clinical practice. One of the barriers to implementation is the lack of evidence about improvement in health outcomes. The NHGRI is funding several genomic medicine implementation projects and has expressed interest in harmonizing outcomes of interest across projects. Based on discussions at the January, 2018 eMERGE meeting, there is interest in eMERGE taking the lead on this. A project to compare eMERGE outcomes with the ClinGen Actionability Working Group Evidence-based Summaries was proposed. This idea was supported and the Outcomes Working Group was tasked to lead the project. Geisinger completed a pilot comparison of its outcomes with the ClinGen summaries and will present this to the Outcomes WG on March 5. |
| **Outline of Project** | We hope that a representative from each site will take its site-specific outcomes and compare these to the ClinGen Actionability Working Group Evidence-based Summaries. If some sites elect not to participate, another author will perform the comparison for the outcomes. This will provide a large group of genomic medicine outcomes from 2 different NHGRI-funded projects that will provide valuable direction for the harmonization project. It is hoped that this will inform other projects about outcomes that can be measured across multiple projects. Common outcomes across these projects could influence the prioritization of outcomes for sites looking to evaluate the implementation of genomic medicine. |
| **Desired Variables**  *(essential for analysis*  *indicated by* ***\*****)* | N/A |
| **Desired Data** | eMERGE outcomes (completed)  ClinGen Actionability Working Group Evidence-based Summaries (posted) |
| **Planned Statistical Analyses** | N/A Descriptive study |
| **Ethical Considerations** | None |
| **Target Journal** | Healthcare (Special Issue: Precision Public Health and Genomic Medicine) |
| **Milestones\*\*** | February 28, 2018 Pilot comparison between Geisinger outcomes and ClinGen evidence summaries (completed)  March 1, 2018 Circulation of Concept Sheet  March, 2018 Comparison of all eMERGE outcomes to ClinGen evidence summaries  April-May, 2018 Manuscript preparation  May 30, 2018 Manuscript submission |

***\*\**** *This section should include the timeline for completion of project, including: approval, project duration, first and second draft of the paper and submission.*